

Case Information

111847-CV | Sarah Palmquist, et al vs. The Hain Celestial Group, Inc., et al

Case Number

111847-CV

File Date

03/10/2021

Court

149th District Court

Case Type

Injury or Damage - Other

Judicial Officer

Holder, Terri

Case Status

Filed

Party

Plaintiff

Palmquist, Sarah

Aliases

ANF E.P.

Active Attorneys▼

Lead Attorney

Arnold, Kurt B.

Retained

Plaintiff

Palmquist, Grant

Aliases

ANF E.P.

Active Attorneys▼

Lead Attorney

Arnold, Kurt B.

Retained

Minor Child (Participant)

E.P.

Defendant

The Hain Celestial Group, Inc.

Active Attorneys▼

Lead Attorney

Cano, Brian G.

Retained

Defendant

Whole Foods Market Inc.

Aliases

AKA Whole Foods Market Rocky Mountain/Southwest, L.P.

Events and Hearings

03/10/2021 Original Petition (1-10 Plaintiffs) (OCA) ▼

Plaintiff's Original Petition - Sarah Palmquist, et al

Comment

Plaintiff's Original Petition - Sarah Palmquist, et al

03/10/2021 Request ▼

Process Request

Comment

Process Request

03/10/2021 Jury Fee Paid ▼

Comment

Sarah Palmquist, Grant Palmquist

03/10/2021 Docket Sheet ▼

Docket Sheet

03/10/2021 Citation ▼

Served

03/16/2021

Served

03/12/2021

03/15/2021 Service Returned ▼

198013 Whole Foods Market, Inc. Citation

Comment

198013 Whole Foods Market, Inc. Citation served on 3-12-2021

03/18/2021 Service Returned ▼

198012 The Hain Celestial Group, Inc - Citation

Comment

198012 The Hain Celestial Group, Inc - Citation - Served on 3-16-2021

03/30/2021 Petition ▼

First Amended Petition

Comment

First Amended Petition

04/05/2021 Answer ▼

Defendant's Original Answer - The Hain Celestial Group, Inc.

Comment

Defendant's Original Answer - The Hain Celestial Group, Inc.

04/06/2021 Jury Fee Paid ▼

Comment

The Hain Celestial Group, Inc.

Documents

Plaintiff's Original Petition - Sarah Palmquist, et al

Process Request

Docket Sheet

198012 - The Hain Celestial Group, Inc. - Citation

198013 - Whole Foods Market Inc. - Citation

198013 Whole Foods Market, Inc. Citation

198012 The Hain Celestial Group, Inc - Citation

First Amended Petition

Defendant's Original Answer - The Hain Celestial Group, Inc.

111847-CV

CAUSE NO. _____

Sarah Palmquist, Individually

and as Next Friend of

E.P., a Minor,

and Grant Palmquist,

Plaintiffs,

v.

The Hain Celestial Group, Inc.; and

Whole Foods Market, Inc.

Defendants.

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IN THE DISTRICT COURT OF

BRAZORIA COUNTY, TEXAS

____ JUDICIAL DISTRICT

ORIGINAL PETITION

COME NOW, Plaintiffs, Sarah Palmquist, Individually and as Next Friend of E.P., a Minor, and Grant Palmquist (collectively “Plaintiffs”) complaining of The Hain Celestial Group, Inc.; and Whole Foods Market, Inc. (collectively referred to as “Defendants”), and would respectfully show the Court the following:

I.

NATURE OF ACTION

1. A recent Congressional committee report concluded that several commercial baby foods are tainted with significant levels of toxic heavy metals including arsenic, lead, cadmium, and mercury.¹ Both the Food and Drug Administration and the World Health Organization agree that these metals are not only dangerous to human health in general but are

¹ See Exhibit 1: “Baby Foods Are Tainted with Dangerous Levels of Arsenic, Cadmium, and Mercury,” Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, February 4, 2021.

particularly dangerous to infants and young children, who are highly vulnerable to their neurotoxic effects. Specifically, studies have shown that infants and children exposed to high levels of these toxic metals have a high risk of developing serious neurological and developmental disorders. In short, “[t]oxic heavy metals endanger infant neurological development and long-term brain function.”²

2. The Hain Celestial Group, Inc. (“Hain”) sells organic baby food nationwide under the “Earth’s Best Organic” brand name. As the Report points out, Hain knew that its baby food contained high levels of toxic metals yet chose to continue to sell its products to children while hiding the true nature of their contents.

3. Plaintiffs Grant and Sarah Palmquist were innocent consumers who purchased the Earth’s Best Organic products convinced that they were buying the highest quality and safest nutrition available for their infant child E.P. Sadly, Hain’s products have severely and permanently damaged E.P.’s brain and neurological function. Plaintiffs bring this suit for damages they have suffered due to Defendants’ production, marketing, distribution, and sale of baby food that contained unsafe levels of toxic heavy metals that have permanently injured E.P.

II.

JURISDICTION

4. Plaintiffs’ claims against all defendants are intended to and do arise exclusively under the laws of Texas.

² *Id.* at 2.

5. The Court has jurisdiction over this case because Plaintiffs seek damages within its jurisdictional limits. Further, this case is not removable because Plaintiffs have not made any federal claims and complete diversity is lacking. 28 U.S.C. § 1332(c)(1). Plaintiffs and Defendant Whole Foods Market, Inc. are residents of the state of Texas. In addition, to the absence of federal question or diversity jurisdiction, removal jurisdiction does not exist as Whole Foods Market, Inc. is a corporate citizen of Texas. *See* 28 U.S.C. § 1441(b)(2) (“A civil action otherwise removable solely on the basis of jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.”).

III.

VENUE

6. Venue is proper in this County pursuant to Texas Civil Practice and Remedies Code Section 15.002(a)(1) because all or a substantial part of the events or omissions giving rise to the claim occurred in this County. Specifically, Plaintiffs are residents of Brazoria County. Further, Brazoria County is the place where E.P. consumed the majority of Earth’s Best Organic products that caused his injuries, thus Plaintiffs’ cause of action accrued here. *See* TEX. CIV. PRAC. & REM. CODE 15.002(a)(4).

IV.

DISCOVERY

7. Plaintiffs request that discovery in this matter be conducted under Level 2 of the Texas Rules of Civil Procedure.

V.

PARTIES

8. Plaintiff Sarah Palmquist resides in Texas and is E.P.’s natural mother. Sarah Palmquist brings claims individually and on behalf of and as next friend of her minor child E.P.

9. Plaintiff Grant Palmquist resides in Texas and is E.P.’s natural father.

10. The Hain Celestial Group, Inc., is a Delaware corporation with its principal place of business in New York. Hain sells its baby food under the “Earth’s Best Organic” brand name. Earth’s Best Brand baby food is sold nationwide, including throughout the state of Texas. Hain Celestial Group, Inc. can be served with process through its registered agent: CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

11. Defendant Whole Foods Market Inc. is a Texas corporation with its principal place of business in Austin, Texas. Whole Foods Market, Inc. sells Earth’s Best Brand baby food at its Texas locations including at the 4004 Bellaire Blvd, Houston, TX 77025 location where Plaintiffs purchased baby food for E.P. Whole Foods Market, Inc. can be served via its registered agent: CT Corporation System, at 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

VI.

FACTS

The February 4, 2021 Committee Report

12. In August 2019, the FDA received a secret slide presentation from Hain, the maker of Earth’s Best Organic baby food, that revealed the presence of high levels of toxic heavy metals in Hain’s finished baby food products. The presentation, entitled “FDA Testing Results Investigation” revealed that half of Hain’s finished rice products tested contained 100 ppb (parts per billion) or more of organic arsenic with one product registering as high as 129

ppb. This represents a level that matches or exceeds the FDA's "dangerously high" 100 ppb level for inorganic arsenic for infant rice cereal.

13. The FDA learned that Hain's policy to test ingredients severely underrepresented the levels of heavy toxic metals in Hain's finished baby food products. In fact, Hain's finished baby food products contained between 28% and 93% more inorganic arsenic than Hain estimated it would find based on Hain's ingredient testing method. Hain tested several products for the FDA presentation and found that all of its finished baby food products contained higher levels of arsenic than were reflected in tests of Hain's individual raw ingredients. These tests put the FDA on notice that Hain's finished baby foods posed a high risk to babies that consumed Hain products.

14. Armed with this knowledge, the United States House of Representatives Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy investigated Hain and several other organic baby food providers and subsequently released a report entitled "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury." The Report gathered findings regarding the presence of heavy toxic metals in organic baby food products like Hain's Earth's Best Organic line. Hain provided the Subcommittee with its internal testing policies, test results for both its ingredients and finished products, and documentation regarding Hain's policies as to its ingredients and finished products that exceeded its internal testing limits. The Report outlines several disturbing findings regarding the level of dangerous heavy metals in Hain's organic baby food products.

Hain products contain high levels of toxic metals.

15. Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals that are extremely dangerous to human health and particularly dangerous to babies and children

especially when consumed in high levels. Babies and children are most vulnerable to the damaging neurotoxic effects these metals can have on the neurological system where even low levels of exposure can cause irreversible brain damage.

16. According to the Report, Hain distributed and sold its organic baby food products despite these products containing dangerously high amounts of arsenic, lead, cadmium, and mercury. Hain's internal company standards permitted sale of its products despite these dangerously high levels of these toxic metals. Hain's internal policies set a standard of 200 ppb for arsenic, lead, and cadmium (the Report found that Hain did not test for mercury) in some of its ingredients. Sadly, Hain far exceeded its internal standards and used ingredients containing 353 ppb lead and 309 ppb arsenic. To compound matters, Hain likely added additional ingredients, like its vitamin/mineral pre-mix, that also contained high levels toxic heavy metals.

Heavy toxic metals like those in Hain's baby food products are a danger to young children.

17. When babies and young children are exposed to heavy toxic metals, the effects can be devastating. "Babies' developing brains are 'exceptionally sensitive to injury caused by toxic chemicals, and several developmental process have been shown to be highly vulnerable to chemical toxicity.'"³ The risk of injury and developmental issues is particularly high in infants due to babies' inability to absorb heavy toxic metals in high amounts. Exposure to heavy toxic metals in early developmental stages can lead to untreatable and permanent brain damage. Studies have shown that exposure to high amounts of lead, for example, can cause IQ loss, brain tumors, and traumatic brain injuries.

³ Ex. 1: Report, at 9.

18. The FDA has declared that inorganic arsenic, lead, cadmium, and mercury can cause severe harmful effects to infants and children and that exposure to these metals can lead to serious illness, severe impairment, and in high doses death. The FDA has cautioned that infants and children face the greatest risk of harm from toxic heavy metal exposure.

19. “Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health . . .”⁴ Arsenic is particularly damaging to the central nervous system and can have devastating effects on cognitive development in children. Boys in particular are more susceptible to arsenic’s neurotoxicity. Studies have shown that exposure to arsenic levels greater than 5 ppb poses a significant threat to cognitive development in young children. In fact, exposure past this “important threshold” leads to decreased global motor, gross motor, and fine motor function scores in young children.

20. Lead is the number two most dangerous substance present in the environment that poses a significant threat to human health. Even small doses of exposure are hazardous to young children and is associated with a broad range of serious health problems. “Lead is associated with a range of bad health outcomes including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth.”⁵ Infants and young children that are exposed to high levels of lead often experience negative neurological effects and decreased brain and nervous system development. Children who have been exposed to lead often suffer from learning disabilities, behavioral disabilities, and low IQ. The cognitive effects of lead exposure to infants and young children are often permanent.

⁴ Ex. 1: Report, at 10.

⁵ Ex. 1: Report, at 11.

21. Cadmium is number seven on the list of dangerous substances present in the environment. Cadmium is associated with IQ loss and development of ADHD. Boys, in particular, suffer higher rates of IQ loss when exposed to high levels of cadmium.

22. Mercury is number three on the list of dangerous substances present in the environment. Higher blood mercury levels in young children has been associated with developmental and cognitive injuries and other behavioral problems.

Hain products contain high levels of arsenic.

23. Inorganic arsenic consumption by babies is unsafe at any level. The FDA has set a maximum inorganic arsenic level of 10 ppb for bottled water. Testing showed that Hain's baby food products contain as much as 129 ppb inorganic arsenic. And that Hain uses ingredients that tested as high as 309 ppb arsenic. Hain also uses a vitamin pre-mix that contains 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic. At least 24 ingredients used by Hain in its organic baby food products tested at more than 100 ppb arsenic. Hain set its own internal standard for arsenic at 200 ppb which allowed it to justify accepting wheat flour and rice that contained between 150-200 ppb arsenic. And Hain's finished baby food products contained more arsenic than the ingredients 100% of the time. In fact, arsenic levels of Hain's finished products were found to be 28-93% higher than the ingredients alone.

Hain products contain high levels of lead.

24. Health experts agree that lead levels in baby food should not exceed 1 ppb. Hain has used ingredients containing as much as 352 ppb lead. A total of 88 ingredients used by Hain tested at levels over 20 ppb lead with six ingredients testing as high as 200 ppb lead. At least 27% of Hain ingredients tested at over 5 ppb lead. And not a single ingredient tested showed levels below 1 ppb lead. Hain set an internal limit of 200 ppb for lead in five of its

ingredients. These levels are 40 times higher than the FDA's guidance for lead ppb in bottled water. These standards surpass every existing regulatory standard for lead.

Hain products contain high levels of cadmium.

25. The World Health Organization has set a standard of 3 ppb cadmium while Consumer Reports advises a limit of 1 ppb cadmium in fruit juices. Testing showed that Hain used ingredients in its baby food products containing up to 260 ppb cadmium. And testing revealed that 102 Hain ingredients tested over 20 ppb cadmium—20 times the level recommended by Consumer Reports.

Hain products contain high levels of mercury.

26. The EPA has capped mercury in drinking water at 2 ppb. Consumer advocates urge even stricter standards for baby food products from companies like Hain. Some groups have called for a goal of no measurable amount of mercury in baby food. From the documents produced to the Subcommittee by Hain, there is no indication that Hain even tests for mercury in its finished products.

Hain distributes its products nationwide, including to Texas Whole Foods stores.

27. Hain distributes and sells its Earth's Best Organic baby food products throughout the country using large retail chains including Whole Foods, Target, Smiths Food and Drug, Walgreens, CVS Pharmacy, and Randalls Food Market. Hain's products are also available through online retailers like Amazon, Instacart, and Walmart.

Plaintiffs purchased Earth's Best products for their son E.P.

28. Dr. Sarah Palmquist, as a board-certified radiologist and Assistant Professor with M.D. Anderson, and Grant Palmquist, as a Logistics Analyst, understand that what a child eats lays the foundation for their development and their future. Plaintiffs, Sarah and Grant Palmquist,

conducted significant research into the food that they would provide their son. After reviewing the products on the market, the Palmquists decided that Earth's Best was the best organic baby food on the market and believed that they were providing their son with the highest quality and safest nutrition possible. Dr. Sarah and Grant Palmquist were loyal Earth's Best customers and purchased these products from Whole Foods.

E.P. consumed primarily Earth's Best products throughout his developmental years.

29. As a newborn infant, E.P. was placed on Earth's Best Organic Dairy Infant Formula with Iron to supplement the breast milk being provided by his mother. From E.P.'s birth until eight months of age, E.P. would consume approximately 2-3 cans of Organic Dairy Infant Formula per month. E.P. drank Earth's Best formula nearly exclusively. At the age of six months, E.P. was introduced to Earth's Best Organic Rice Cereal and then quickly introduced to other Earth's Best baby foods that included Earths' Best Whole Grain Oatmeal Cereal, Earth's Best Whole Grain Oatmeal Cereal, Earth's Best Stage 1 foods, which included Sweet Potatoes, First Peas, First Bananas, First Prunes, First Apples, and First Pears.

30. E.P. was switched fully over to the Earth's Best formula when Dr. Sarah Palmquist had to cease breastfeeding at the age of eight months. At this point, E.P.'s consumption of Earth's Best Organic Dairy Infant Formula increased to 4-5 canisters per month in addition to his eating of the Earth's Best cereals and Stage 1 foods. Shortly after learning to eat Stage 1 foods, E.P. graduated to Stage 2 foods that included Earth's Best Winter Squash, Earth's Best Sweet Potato & Chicken Dinner, Earth's Best Pears & Mangos, Earth's Best Vegetable Turkey Dinner, Earth's Best Spinach & Potato, and Earth's Best Sweet Potatoes. When E.P. was developmentally ready and of age, he again graduated to the next level of foods. The Earth's Best Stage 3 foods that E.P. ate included Earth's Best Tender Chicken & Stars, Earth's Best Apple Cinnamon Oatmeal, Earth's

Best Vegetable Soup, Earth's Best Spring Vegetables & Pasta, Earth's Best Sweet Peas & Creamed Spinach Medley, and Earth's Best Zucchini Broccoli Medley.

31. As E.P. approached ten to eleven months until approximately three years old, E.P. also ate the pouches made by Earth's Best that includes Earth's Best Organic Beef Medley with Vegetables, Earth's Best Organic Chicken Pot Pie, Earth's Best Organic Turkey Quinoa Apple Sweet Potato, Earth's Best Organic Pear Carrot Apricot, and Earth's best Organic Fruit Yogurt Smoothies. Being a toddler, E.P. also devoured snacks, these snacks included Earth's Best Sunny Days Snack Bars (Apple), Earth's Best Organic Garden Veggie Straws, Earth's Best Organic Crunchin' Crackers, and Earth's Best Organic Sunny Days Snack Bars (Strawberry). E.P. consumed Earth's Best baby food nearly exclusively.

***As a result of high levels of toxic metals in his system,
E.P. now suffers from severe brain and bodily injuries.***

32. E.P. was born on September 27, 2014, to Sarah and Grant Palmquist after a healthy and uneventful pregnancy by his mother, Dr. Sarah Palmquist. Following routine postnatal care, E.P. was released home into the care of his parents. E.P. was a healthy, happy, and social baby boy and was excelling at meeting his developmental milestones until shortly before he turned three years old when he began to exhibit symptoms of brain damage. E.P. went from a vibrant, active, and talkative toddler to suffering from concrete and sustained abnormalities that would be diagnosed as brain damage resulting from confirmed heavy metal toxicity. E.P., at the current age of 6, now requires round-the-clock care, is not toilet trained, suffers from gastrointestinal issues, has a significant loss of fine and gross motor skills, has aggression issues, and is unable to communicate with his parents and caregivers. E.P. requires constant monitoring to ensure that he does not injure himself or elope.

33. In the period between May to August 2017, at 2 years and 8 months old, E.P. demonstrated a rapid regression in all areas of development. The loquacious two-year-old was now unable to communicate and became clumsy, slow, and demonstrated severely regressed gross and fine motor function. E.P. additionally developed chronic diarrhea which often occurred up to 6-8 times per day, and a severely bloated stomach.

34. From August 2017 through December 2017, Plaintiffs Sarah and Grant Palmquist, visited with several doctors and therapists in an attempt to diagnose, treat, and manage the rapid regression that E.P. was experiencing. In December 2017, the Palmquists consulted with a developmental pediatrician with MAPS (Medical Academy of Pediatric Special Needs) certification. After taking an extensive clinical history, evaluating, and observing, E.P., the doctor initiated a medical workup that included testing for heavy metal toxicity, standard bloodwork, MTHFR genetic variant analysis and a stool sample. The two tests ordered to evaluate for heavy metal toxicity were a hair sample, which analyzes the amount of excreted heavy metals, and a urine porphyrins test, which analyzes ratios of abnormal porphyrins excreted in the urine. In a urine porphyrin test, the presence and concentration of various abnormal porphyrins correspond to levels of heavy metals in the body.

35. E.P. was found to have severe heavy metal toxicity. Both tests showed a high level of heavy metals, notably greater than the 99th percentile on the hair test. The doctor said that it was one of the worst cases the doctor had ever seen. At this time, the reports of high metal toxicity in Earth's Best baby foods were not known to the general public. To address the heavy metal toxicity, the doctor recommended low-dose frequent oral chelation. A method of chelation that involves taking a low-dose oral chelator based on the patient's weight and is taken at 4-hour intervals for 72 hours, followed by 4 days off. This low-dose chelation method continued for months where

E.P.'s family members were required to wake every few hours three days a week to administer the medication. E.P. then started transdermal chelation for continued efforts to lower E.P.'s heavy metal load.

36. The stool test demonstrated an abnormal bacterial overgrowth of yeast and Clostridia bacteria. Plaintiffs were told that the presence of heavy metal toxicity can result in gastrointestinal tract dysbiosis. For this dysbiosis, or microbial imbalance, E.P. was treated with antibiotics and antifungals for three months and then placed on maintenance medication.

37. In December 2017, Plaintiffs, Dr. Sarah Palmquist and Grant Palmquist, requested a 23-hour electroencephalogram (EEG) to rule out a seizure disorder as the reason for E.P.'s unexplained regression. Plaintiffs were aware that sometimes seizure activity can be present without the typical clinical presentations and that sometimes the only symptom is the loss of language. This EEG was interpreted as negative for a seizure disorder. Again, the Plaintiffs were left without a diagnosis for their son's decline and extreme heavy metal toxicity.

38. E.P. was again tested for heavy metals with a urine porphyrin test in August 2018, and again E.P. demonstrated an extremely high toxic load. The physician who ordered the test is another MAPS physician who specializes in pediatric acute onset neuropsychiatric syndrome. The doctor stated that it was one of the worst cases he had ever seen and was baffled by the high load of heavy metals and that he was "loaded with mercury." Blood work was ordered by another of E.P.'s treating physicians to test for infectious or autoimmune causes for epilepsy. Again, no other definitive cause of E.P.'s severe toxic heavy metal load was found.

39. Further testing and treatment that Plaintiffs endured in their search for a cause of E.P.'s brain damage and developmental regression included whole exome genetic sequencing ordered by a pediatric neurologist. This genetic sequencing was ordered on E.P., as well as Dr.

Sarah Palmquist and Grant Palmquist. No genetic abnormalities tested for on that exam were found in E.P., Sarah Palmquist, or Grant Palmquist. The doctor performed additional testing, and this included genetic testing for chromosomal deletions and translocations, inherited mitochondrial disorders, and metabolic disorders; all of which were negative. Due to newly discovered genetic mutations, in January 2021, an additional query was made on E.P.'s genetic data and this too was negative.

40. In April 2019, another 23-hour EEG was ordered after E.P. developed a further loss of language after the age of 3 in combination with Sarah Palmquist witnessing what she thought may be signs of a clinical seizure, notably uncontrollable writhing movements on the floor as well as abnormal movements of the facial muscles. The April 2019 EEG was abnormal, consistent with diffuse bilateral frontotemporal epileptiform discharges, diffuse slowing, and mild encephalopathy. This result of the EEG was not consistent with any known childhood epilepsy disorder. Research demonstrates that heavy metal toxicity can induce seizures. E.P. was then placed on an anti-epileptic drug in which he remains on today. During the time seizure activity was suspected by Dr. Sarah Palmquist and treatment for seizures was initiated, chelation therapy was stopped for safety reasons. Once the seizures were diagnosed and treated with anti-epileptic medication, E.P. had a follow-up EEG that demonstrated no seizure activity in September 2019. Chelation was reinitiated until treatment was started for his gastrointestinal injuries.

41. From September 2019 through December 2019, Plaintiffs consulted with two physicians specializing in gastrointestinal (GI) disorders in children. These doctors were able to diagnose diffuse inflammation throughout the GI tract. While E.P. was initially placed on a systemic steroid and saw improvement in his GI issues, steroids are not a long-term answer to a chronic injury. Effort was then turned to healing his GI tract since a large portion of detoxification

occurs through the bile excreted from the liver. E.P. was placed on several antibiotics to eradicate the dysbiotic bacteria, and then high doses of probiotics. After treatment, some of E.P.'s GI issues have improved in terms of consistency and frequency of bowel movements. However, the brain damage resulting in profound developmental delay and intellectual impairment remains.

42. Extensive diagnostic testing, including lab work, genetic sequencing, EEGs, a brain MRI, and expert clinical assessment by multiple physicians have ruled out numerous potential other causes of E.P.'s brain damage. Abnormal pregnancy, birth trauma, genetic causes, structural brain abnormalities, childhood epilepsy disorder, metabolic, and infectious causes have also been excluded. Further, E.P. has never experienced trauma to his head nor any other region of his body. While some of E.P.'s gastrointestinal issues have improved, E.P. remains profoundly brain damaged. E.P. functions at the level of a child aged two years or younger. His communication skills are in the <1 percentile for his age and he is not even able to undergo IQ testing due to his severe impairments. Numerous peer reviewed authoritative articles have evidenced the association between brain damage and GI issues in infants when chronically exposed to heavy metals in infancy. E.P. has been irreparably harmed from his chronic heavy metal exposure during his pivotal development as an infant and young child due to Earth's Best baby formula and baby food.

VII.

CAUSES OF ACTION

A. Negligence against All Defendants

43. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

44. Plaintiffs were injured because of Defendants' negligence and gross negligence when Defendants negligently:

- a. designed, produced, marketed, and distributed baby food products with dangerous levels of heavy toxic metals;
- b. failed to warn Plaintiffs regarding the dangerous amounts of heavy toxic metals present in Hain's Earth's Best Organic baby food products;
- c. failed to properly label its products knowing that the products contained dangerous levels of heavy toxic metals;
- d. failed to comply with applicable standards, rules, and regulations regarding safe levels of arsenic, lead, cadmium, and mercury;
- e. failed to adequately test its ingredients and its final products for dangerous levels of heavy toxic metals;
- f. committed other acts deemed negligent and grossly negligent.

45. Defendants owed Plaintiffs a duty to provide safe products and to adequately warn them of the levels of heavy toxic metals contained in those products. As outlined above, Defendants breached those duties. These breaches were both the cause in fact and proximate cause of Plaintiffs' injuries. As a result of Defendants' negligence, Plaintiff E.P. sustained severe injuries to his body, including severe brain damage and neurological injuries from which he will never fully recover. His injuries have resulted in physical pain, mental anguish, and other medical problems. Plaintiffs Grant and Sarah Palmquist have suffered severe pain, mental anguish, and emotional distress due to their son's injuries. Plaintiffs have incurred and will continue to incur pharmaceutical and medical expenses in connection with E.P.'s injuries. Plaintiffs are entitled to recover for their injuries. Defendants' actions were done with reckless

disregard to a substantial risk of bodily injury. Accordingly, Plaintiffs are entitled to punitive damages.

46. Furthermore, Plaintiffs are entitled to punitive damages because Defendants' actions were grossly negligent. Defendants acted with flagrant and malicious disregard for Plaintiff E.P.'s health and safety. Defendants knew the extreme risks posed by the high levels of heavy toxic metals in their baby food products but ignored those risks and intentionally sold the products knowing of the dangers to babies and children like Plaintiff. Further, Defendants failed to warn Plaintiffs of the extreme risk and hazard Earth's Best Organic baby foods posed to Plaintiff. Defendants had actual, subjective awareness of the risk and consciously disregarded such risk by allowing Plaintiffs to buy the Earth's Best Organic products and to feed them to E.P. Defendants knew consumers like Plaintiffs would rely on Hain's claims, purchase the baby food based on those claims, and feed it to children like E.P. These acts were willful, wanton, and grossly negligent.

B. Products Liability against The Hain Celestial Group, Inc.

47. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

48. Plaintiffs are "persons" as defined in Texas Business and Commerce Code § 17.45(3).

49. As defined in Texas Business and Commerce Code §§ 17.45(9) and (13), Hain knowingly and intentionally engaged in false, misleading, and deceptive acts that caused Plaintiffs' injuries.

50. Specifically, Hain knowingly, that is with actual awareness of the falsity, deception, and unfairness of its acts, sold its Earth's Best Organic baby food products with

high, dangerous levels of heavy toxic metals. Hain intentionally did so with the specific intent that Plaintiffs would act in detrimental reliance on the falsity or deception or in detrimental ignorance of the unfairness of Hain's claims. Plaintiffs bought and fed E.P. Hain's Earth's Best Organic baby food products almost exclusively due to them being widely available and due to Hain's claims that its products were high quality and safe. E.P.'s injuries are a direct result of Hain's deceptive practices.

51. Further, Hain designed, tested, manufactured, marketed, distributed, and/or sold its Earth's Best baby food products with design, manufacturing, and/or marketing defects.

52. **Manufacturing Defect:** Hain's baby food products were designed, manufactured, distributed, and/or sold with one or more manufacturing defects. Specifically:

- a. Hain provided its products to consumers like Plaintiffs in a defective condition with high levels of heavy toxic metals that rendered the products unreasonably dangerous and unsafe for use by babies and small children;
- b. Hain's products deviated in quality from suggested industry standards and were produced with ingredients that contained high toxic levels of arsenic, lead, cadmium, and mercury;
- c. Hain failed to properly test its final products to ensure that the levels of heavy toxic metals contained in them were below levels established by applicable regulations and accepted by industry standards;
- d. When the products left Hain's custody or control they had been manufactured defectively;
- e. The design, manufacturing, and/or marketing defects rendered the baby

food products in question unreasonably dangerous.

53. The manufacturing defects that rendered the baby food products unreasonably dangerous were the producing, proximate, and contributing cause of Plaintiffs' injuries.

54. **Design Defect:** Hain's Earth's Best baby food products were designed, manufactured, distributed, and sold with one or more design defects.

- a. Hain designed its Earth's Best Organic baby food products in an unreasonably dangerous manner while safer alternative designs were available at the time of the design and production of the food products in question. Specifically, Hain used ingredients that contained high levels of heavy toxic metals that were not removed during production. Better, safer ingredients were available for Hain to use in its products.
- b. Hain either knew or should have known that safer ingredients were available that would reduce the level of heavy toxic metals in their final products to levels that are considered safe by health experts and that comply with federal regulations and industry standards.
- c. The safer alternative designs would have prevented or significantly reduced the previously mentioned risks without substantially impairing the products. In fact, had Hain used safer ingredients it would have served the purpose of ensuring that the final products matched the claims Hain made about them.
- d. The safer alternative design was economically and technologically feasible at the time the baby food products left Hain's control. Safer ingredients are readily available as are testing methods to ensure the

safety of the baby food products.

- e. Hain either knew or should have known that the design, manufacturing, and marketing defects deviated from the planned specifications for the baby food products in question.
- f. The design defects rendered the baby food products unreasonably dangerous.

55. The baby food products' defective design was the producing, proximate, and contributing cause of Plaintiffs' injuries.

56. **Marketing Defects and Failure to Warn:** The baby food products in question were designed, manufactured, distributed, and sold with one or more marketing defects.

- a. There was an unreasonable risk in the intended or reasonably foreseeable use of Hain's Earth's Best Organic baby food products. Specifically,
- b. Hain failed to adequately warn Plaintiffs of the risk relating to feeding their child baby food containing high levels of heavy toxic metals. Specifically, Hain did not provide adequate warning labels indicating that consuming the baby food products could cause severe neurological injuries. Hain failed to instruct Plaintiffs regarding the risks and failed to instruct Plaintiffs on how to avoid the dangers.
- c. Including appropriate warnings and providing complete information regarding the contents of its products would have been both technologically and economically feasible for Hain when the products left its custody and control.
- d. The marketing defects rendered the baby food products unreasonably

dangerous.

57. Hain's failure to warn and the marketing defects relating to the products in question were the producing, proximate, and contributing cause of Plaintiffs' injuries.

58. As a direct and proximate result of Hain's conduct, Plaintiff E.P. sustained severe injuries to his body and mind that resulted in severe, permanent cognitive and neurological injuries, physical pain, mental anguish, and other medical problems. E.P. will never fully recover from his injuries and will continue to suffer the debilitating effects of his neurological injuries throughout the remainder of his life. E.P. will be severely limited and unable to function normally. Additionally, Plaintiffs Grant and Sarah Palmquist have suffered mental anguish, emotional trauma, and financial loss due to E.P.'s injuries. Plaintiffs have incurred and will continue to incur pharmaceutical and medical expenses in connection with E.P.'s injuries.

59. Plaintiffs are also entitled to exemplary damages because of Hain's actions and inactions. Hain's conduct rises to the level of gross negligence. Hain was subjectively aware that its baby food products contained high levels of heavy toxic metals and were subjectively aware that these neurotoxins would likely injure infants and young children. Hain's actions and inactions when viewed objectively, subjected Plaintiffs to an extreme degree of risk.

C. Breach of Warranties against Whole Foods Market, Inc.

60. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

61. Whole Foods Market, Inc. sold Hain's Earth's Best Organic baby food products and in doing so impliedly warranted to the public generally and specifically that the products were safe for consumption by infants and young children.

62. Whole Foods knew or had reason to know that consumers like Plaintiffs would purchase the Hain products due to their being advertised as safe and high-quality organic baby food.

63. Whole Foods' implied warranty was incorrect given the high levels of heavy toxic metal Hain's baby food products contained.

64. Plaintiffs relied on Whole Foods' representations that Hain's Earth's Best Organic baby food products were safe and of the highest quality.

65. If Hain's products were as advertised, Plaintiffs would not have been injured by the product. Hain and Whole Foods markets the Earth's Best Organic baby food products as safe, natural, and organically produced. If the products had been in a condition as advertised, E.P. would not have been exposed to extremely high, toxic levels of arsenic, lead, cadmium, and mercury and would not have suffered cognitive brain injuries as a result.

66. Plaintiffs' injuries were sustained because of Whole Foods' implied warranties.

VIII.

DAMAGES

67. Plaintiffs seek damages in excess of \$1,000,000.00. Specifically, as a direct and proximate result of Defendants' acts and omissions, Plaintiff E.P. has suffered serious, permanent, and disabling injuries. As a further result of such injuries, Plaintiff has also suffered physical pain, discomfort, disfigurement, physical impairment and extraordinary emotional pain and mental anguish. Plaintiff will continue to suffer such damages into the future, if not for the balance of his natural life.

68. In addition, as a direct and proximate result of Defendants' acts and omissions, Plaintiffs Grant and Sarah Palmquist have incurred reasonable and necessary medical and

healthcare expenses, which expenses will continue to be incurred in the future. All of these damages which have been suffered by Plaintiffs herein have a monetary value which greatly exceeds the minimum jurisdictional limits of this Court. Plaintiffs pray for relief and judgment as follows:

- Compensatory damages against Defendants;
- Actual damages;
- Loss of services and earnings of an un-emancipated minor;
- Consequential damages;
- Pain and suffering;
- Exemplary damages;
- Past and future mental anguish;
- Past and future impairment;
- Past and future disfigurement;
- All other damages allowable under Texas law;
- Interest on damages (pre and post-judgment) in accordance with the law;
- Costs of Court;
- Expert witness fees;
- Costs of copies of depositions; and
- Such other and further relief as the Court may deem just and proper.

IX.

JURY TRIAL DEMANDED

69. Plaintiffs hereby request a trial by jury on all claims and submit their jury fee

herewith.

X.

PRAYER

Plaintiffs pray that this citation issue and be served upon Defendants in a form and manner prescribed by law, requiring that Defendants appear and answer, and that upon final hearing, Plaintiffs have judgment against Defendants in a total sum in excess of the minimum jurisdictional limits of this Court, pre-judgment and post-judgment interests, all costs of Court, exemplary damages, and all such other and further relief, to which they may show themselves justly entitled.

Respectfully Submitted,

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EXHIBIT 1



Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury



Staff Report

**Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives**

February 4, 2021

oversight.house.gov

EXECUTIVE SUMMARY

Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The Food and Drug Administration and the World Health Organization have declared them dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects. Even low levels of exposure can cause serious and often irreversible damage to brain development.

On November 6, 2019, following reports alleging high levels of toxic heavy metals in baby foods, the Subcommittee on Economic and Consumer Policy requested internal documents and test results from seven of the largest manufacturers of baby food in the United States, including both makers of organic and conventional products:

- Nurture, Inc. (Nurture), which sells Happy Family Organics, including baby food products under the brand name HappyBABY
- Beech-Nut Nutrition Company (Beech-Nut)
- Hain Celestial Group, Inc. (Hain), which sells baby food products under the brand name Earth's Best Organic
- Gerber
- Campbell Soup Company (Campbell), which sells baby food products under the brand name Plum Organics
- Walmart Inc. (Walmart), which sells baby food products through its private brand Parent's Choice
- Sprout Foods, Inc. (Sprout Organic Foods)

Four of the companies—Nurture, Beech-Nut, Hain, and Gerber—responded to the Subcommittee's requests. They produced their internal testing policies, test results for ingredients and/or finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits.

Walmart, Campbell, and Sprout Organic Foods refused to cooperate with the Subcommittee's investigation. The Subcommittee is greatly concerned that their lack of cooperation might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

FINDINGS

1. According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function. Specifically, the Subcommittee reports that:

ARSENIC was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.
- Hain (Earth's Best Organic) sold finished baby food products containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic.
- Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as "crumb softness."
- Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

LEAD was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.
- Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.
- Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.
- Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.

CADMIUM was present in baby foods made by all responding companies.

- Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.
- Hain (Earth's Best Organic) used 102 ingredients in its baby food that tested over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.

- Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium.
- Seventy-five percent of Gerber's carrots contained cadmium in excess of 5 ppb, with some containing up to 87 ppb cadmium.

MERCURY was detected in baby food of the only responding company that tested for it.

- Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.
- Beech-Nut and Hain (Earth's Best Organic) do not even test for mercury in baby food.
- Gerber rarely tests for mercury in its baby foods.

These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level.

2. Internal company standards permit dangerously high levels of toxic heavy metals, and documents revealed that the manufacturers have often sold foods that exceeded those levels.
 - Nurture (HappyBABY) sold all products tested, regardless of how much toxic heavy metal the baby food contained. By company policy, Nurture's toxic heavy metal testing is not intended for consumer safety. The Food and Drug Administration (FDA) has only finalized one standard—100 ppb inorganic arsenic in infant rice cereal—and Nurture set its internal standard for that product 15% higher than the FDA limit, at 115 ppb.
 - Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.
 - Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified deviations above its ingredient testing

standards based on “theoretical calculations,” even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

3. The Subcommittee has grave concerns about baby food products manufactured by Walmart (Parent’s Choice), Sprout Organic Foods, and Campbell (Plum Organics). These companies refused to cooperate with the Subcommittee’s investigation. The Subcommittee is greatly concerned that their lack of cooperation might obscure the presence of even higher levels of toxic heavy metals in their baby food products, compared to their competitors’ products.
 - Walmart sells Parent’s Choice and Parent’s Choice Organic products for babies as young as four months.
 - Sprout Organic Foods sells organic products for babies as young as six months. It is owned by North Castle Partners, a Greenwich, Connecticut–based private equity firm.
 - Campbell sells Plum Organics products for babies as young as four months.
 - Independent testing of Walmart, Sprout Organic Foods, and Campbell products has confirmed that their baby foods contain concerning levels of toxic heavy metals.
4. The Trump administration ignored a secret industry presentation to federal regulators revealing increased risks of toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain (Earth’s Best Organic), which revealed that:
 - Corporate policies to test only ingredients, not final products, underrepresent the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and 93% higher in the finished products;
 - Many of Hain’s baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic; and
 - Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Hain may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

This presentation made clear that ingredient testing is inadequate, and that only final product testing can measure the true danger posed by baby foods.

The Trump FDA took no new action in response. To this day, baby foods containing toxic heavy metals bear no label or warning to parents. Manufacturers are free to test only ingredients, or, for the vast majority of baby foods, to conduct no testing at all. FDA has only finalized one metal standard for one narrow category of baby food, setting a 100 ppb inorganic arsenic standard for infant rice cereal. But this FDA standard is far too high to protect against the neurological effects on children.

5. The Subcommittee makes the following recommendations:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice;
- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

6. Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and the Trump administration's federal regulators have broken the faith.

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I. THE DANGER OF TOXIC HEAVY METALS TO CHILDREN'S HEALTH

Children's exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior.¹

Babies' developing brains are "exceptionally sensitive to injury caused by toxic chemicals, and several developmental processes have been shown to be highly vulnerable to chemical toxicity."² The fact that babies are small, have other developing organ systems, and absorb more of the heavy metals than adults, exacerbates their risk from exposure to heavy metals.³

Exposure to heavy metals at this developmental stage can lead to "untreatable and frequently permanent" brain damage, which may result in "reduced intelligence, as expressed in terms of lost IQ points, or disruption in behavior."⁴ For example, a recent study estimates that exposure to environmental chemicals, including lead, are associated with 40,131,518 total IQ points loss in 25.5 million children (or roughly 1.57 lost IQ points per child)—more than the total IQ losses associated with preterm birth (34,031,025), brain tumors (37,288), and traumatic brain injury (5,827,300) combined.⁵ For every one IQ point lost, it is estimated that a child's lifetime earning capacity will be decreased by \$18,000.⁶

Well-known vectors of child exposure to toxic heavy metals include lead paint in old housing and water pollution from landfills. Over the decades, a range of federal and state laws and regulations have been passed to protect child health through emissions standards, among other things.

The Food and Drug Administration (FDA) has declared that inorganic arsenic, lead, cadmium, and mercury are dangerous, particularly to infants and children. They have "no established health benefit" and "lead to illness, impairment, and in high doses, death." According to FDA, "even low levels of harmful metals from individual food sources, can

¹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

² Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

³ Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018) (online at www.consumerreports.org/food-safety/heavy-metals-in-baby-food/).

⁴ Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

⁵ David C. Bellinger, *A Strategy for Comparing the Contributions of Environmental Chemicals and Other Risk Factors to Neurodevelopment of Children* (Dec. 19, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/).

⁶ Martine Bellanger et al., *Economic Benefits of Methylmercury Exposure Control in Europe: Monetary Value of Neurotoxicity Prevention* (Jan. 17, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23289875/>).

sometimes add up to a level of concern.” FDA cautions that infants and children are at the greatest risk of harm from toxic heavy metal exposure.⁷

The Subcommittee on Economic and Consumer Policy’s investigation has found another source of exposure: baby foods. According to documents obtained from baby food manufacturers, toxic heavy metals, such as arsenic, cadmium, lead, and mercury are present at substantial levels in both organic and conventional baby foods. Currently, there is no federal standard on, or warning to parents and caregivers about, these toxins.

A. Inorganic Arsenic

Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health, according to the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (ATSDR).⁸ The known health risks of arsenic exposure include “respiratory, gastrointestinal, haematological, hepatic, renal, skin, **neurological and immunological effects, as well as damaging effects on the central nervous system and cognitive development in children.**”⁹

Studies have concluded that arsenic exposure has a “significant negative effect on neurodevelopment in children.”¹⁰ This negative effect is most pronounced in Full Scale IQ, and more specifically, in verbal and performance domains as well as memory. For every 50% increase in arsenic levels, there is an approximately “0.4 decrease in the IQ of children.”¹¹

A study of Maine schoolchildren exposed to arsenic in drinking water found that children exposed to water with an arsenic concentration level greater than 5 parts per billion (ppb) “showed significant reductions in Full Scale IQ, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.” The authors pegged 5 ppb as an important threshold.¹²

Likewise, a study of children in Spain found that increasing arsenic exposure led to a decrease in the children’s global motor, gross motor, and fine motor function scores. Boys in particular were more susceptible to arsenic’s neurotoxicity.¹³

⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

⁸ Agency for Toxic Substances and Disease Registry, *ATSDR’s Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

⁹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (June 1, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23570911/>) (emphasis added).

¹⁰ *Id.*

¹¹ *Id.*

¹² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹³ Antonio J. Signes-Pastor et al., *Inorganic Arsenic Exposure and Neuropsychological Development of Children of 4-5 Years of Age Living in Spain* (Apr. 29, 2019) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/).

B. Lead

Lead is number two on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.¹⁴ Even small doses of lead exposure are hazardous, particularly to children.¹⁵ Lead is associated with a range of bad health outcomes, including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth. According to FDA, lead is especially dangerous to "infants" and "young children." FDA acknowledges that:

High levels of lead exposure can seriously harm children's health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹⁶

Lead exposure severely affects academic achievement in children. Even at low levels, early childhood lead exposure has a negative impact on school performance. Two separate studies of schoolchildren in Detroit and Chicago public schools found a strong inverse relationship between lead exposure and test scores. In the Detroit study, there was a "significant association" between early childhood lead exposure and decreased standardized test performance, with lead exposure strongly linked to an adverse effect on academic achievement.¹⁷ The Chicago study found that higher blood lead concentrations were associated with lower reading and math scores in 3rd grade children. Increased blood lead concentrations correlated with a 32% increase in the risk of failing reading and math.¹⁸

The cognitive effects of early childhood lead exposure appear to be permanent. In one study, adults who previously had lead-associated developmental delays continued to show persisting cognitive deficits, demonstrating the long-lasting damage of lead exposure.¹⁹

¹⁴ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

¹⁵ Philippe Grandjean, *Even Low-Dose Lead Exposure Is Hazardous* (Sept. 11, 2010) (online at <https://pubmed.ncbi.nlm.nih.gov/20833288/>).

¹⁶ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹⁷ Nanhua Zhang et al., *Early Childhood Lead Exposure and Academic Achievement: Evidence From Detroit Public Schools* (Mar. 2013) (online at <http://mediad.publicbroadcasting.net/p/michigan/files/201302/AJPH.2012.pdf>).

¹⁸ Anne Evens et al., *The Impact of Low-Level Lead Toxicity on School Performance Among Children in the Chicago Public Schools: A Population-Based Retrospective Cohort Study* (Apr. 7, 2015) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0008-9>).

¹⁹ Maitreyi Mazumdar et al., *Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-Up Study* (Mar. 30, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/).

Studies have also established a significant association between lead exposure and Attention-Deficit/Hyperactivity Disorder (ADHD).²⁰

C. Cadmium

Cadmium is number seven on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²¹ Cadmium is associated with decreases in IQ, as well as the development of ADHD.

A 2018 study found that cadmium exposure negatively affected children's Full Scale IQ, particularly among boys. Boys exhibiting higher amounts of cadmium exposure had seven fewer IQ points than those exhibiting less cadmium exposure.²² A 2015 study similarly found a significant inverse relationship between early cadmium exposure and IQ.²³

A 2018 study linked cadmium exposure to ADHD, finding that the disorder was more common among children with the highest levels of cadmium exposure as compared to a control group.²⁴

D. Mercury

Mercury is number three on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²⁵ Studies of mercury's effect on childhood development have primarily been conducted by considering the mother's exposure to mercury while pregnant. In these instances, "pre-natal mercury exposure has been consistently associated with adverse subsequent neuro-development."²⁶ And pre-natal mercury exposure is also related to poorer estimated IQ.²⁷ Beyond prenatal exposure, higher blood mercury levels at

²⁰ Gabriele Donzelli et al., *The Association Between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review* (Jan. 29, 2019) (online at www.mdpi.com/1660-4601/16/3/382/htm).

²¹ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²² Klara Gustin et al., *Cadmium Exposure and Cognitive Abilities and Behavior at 10 Years Off Age: A Prospective Cohort Study* (Apr. 2018) (online at www.sciencedirect.com/science/article/pii/S0160412017321025).

²³ Alison P. Sanders et al., *Perinatal and Childhood Exposure To Cadmium, Manganese, And Metal Mixtures And Effects On Cognition And Behavior: A Review Of Recent Literature* (July 5, 2015) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/).

²⁴ Min-Jing Lee et al., *Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony* (June 10, 2018) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/).

²⁵ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²⁶ Margaret R. Karagas et al., *Evidence on the Human Health Effects of Low-Level Methylmercury Exposure* (June 1, 2012) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1104494>).

²⁷ Joseph Jacobson et al., *Relation of Prenatal Methylmercury Exposure from Environmental Sources to Childhood IQ* (Aug. 1, 2015) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1408554>).

“2 and 3 years of age were positively associated with autistic behaviors among preschool-age children.”²⁸

II. TOP BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF INORGANIC ARSENIC, LEAD, CADMIUM, AND MERCURY.

Internal company test results obtained by the Subcommittee confirm that all responding baby food manufacturers sold baby foods tainted by high levels of toxic heavy metals.

A. Inorganic Arsenic

There is no established safe level of inorganic arsenic consumption for babies. Organizations such as Healthy Babies Bright Futures have called for a goal of no measurable amount of inorganic arsenic in baby food.²⁹ Consumer Reports suggests setting inorganic arsenic levels as low as 3 parts per billion (ppb).³⁰ FDA has already set maximum inorganic arsenic levels at 10 ppb for bottled water.³¹ The Environmental Protection Agency (EPA) has similarly set a 10 ppb inorganic arsenic cap on drinking water, as have the European Union (EU) and the World Health Organization (WHO).³²

1. Nurture (HappyBABY) sold finished baby foods after testing showed they contained as much as 180 ppb inorganic arsenic; over 25% of the tested baby food sold by Nurture exceeded 100 ppb inorganic arsenic; on average, Nurture baby food on store shelves has nearly 60 ppb inorganic arsenic.

Nurture is the only baby food manufacturer that appears to regularly tests its finished baby food products for inorganic arsenic content (the others only test ingredients).

²⁸ Jia Ryu et al., *Associations of Prenatal and Early Childhood Mercury Exposure with Autistic Behaviors at 5 Years of Age: The Mothers and Children's Environmental Health (MOCEH) Study* (Dec. 15, 2017) (online at www.sciencedirect.com/science/article/pii/S0048969717316479).

²⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

³⁰ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

³¹ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

³² Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.³³ An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb.

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁴

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	180	ppb	11/01/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

Nurture routinely sold products that exceeded its internal standards. Twenty-nine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb.³⁵

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁶

Product Name	Goal Threshold	Result	Date of Test Report	Disposition
Apple & Broccoli Puffs	100	180	11/01/17	Sell
Banana & Pumpkin Puffs	100	160	10/31/17	Sell
Strawberry & Beet Puffs	100	160	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Purple Carrot & Blueberry Puffs	100	150	11/17/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Sweet Potato & Carrot Puffs	100	122	09/13/18	Sell
Apple Rice Cakes	100	120	02/08/17	Sell

³³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

Blueberry Beet Rice Cakes	100	120	02/08/17	Sell
Purple Carrot & Blueberry Puffs	100	120	10/31/17	Sell
Apple & Broccoli Puffs	100	115	10/15/18	Sell
Strawberry & Beet Puffs	100	114	03/21/19	Sell
Purple Carrot & Blueberry Puffs	100	112	06/05/18	Sell
Apple Rice Cakes	100	110	07/28/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Strawberry & Beet Puffs	100	108	12/10/18	Sell
Strawberry & Beet Puffs	100	108	09/21/18	Sell
Apple & Broccoli Puffs	100	107	05/30/19	Sell
Strawberry & Beet Puffs	100	107	05/22/19	Sell
Strawberry & Beet Puffs	100	105	09/21/18	Sell
Strawberry & Beet Puffs	100	104	08/22/18	Sell
Banana & Pumpkin Puffs	100	103	04/24/19	Sell
Sweet Potato & Carrot Puffs	100	103	04/24/19	Sell
Banana & Pumpkin Puffs	100	101	09/21/18	Sell

The average amount of inorganic arsenic in the baby foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb.

At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above.

For results under 9.54 ppb, Nurture did not differentiate—it marked them all as “<9.54.” Because of this “less than” reporting format, there is no way to know if any of Nurture's products were free of inorganic arsenic.

Summary of Nurture's Inorganic Arsenic Results

180 ppb – Nurture's product with the highest amount of inorganic arsenic: Apple & Broccoli Puffs.
>100 ppb – Over 25% of the baby food products that were tested for inorganic arsenic had over 100 ppb inorganic arsenic.
59.54 ppb – Average amount of inorganic arsenic in all baby food products tested for inorganic arsenic.
>50 ppb – Over 50% of Nurture's baby food products that were tested for inorganic arsenic contained over 50 ppb inorganic arsenic.

2. **Hain (Earth's Best Organic) produced finished baby foods that contained as much as 129 ppb inorganic arsenic; Hain used ingredients in its baby foods with as much as 309 ppb total arsenic.**

Hain does not regularly test finished baby food products for inorganic arsenic content. It typically only tests ingredients. However, when Hain did test a small sample of finished product, it found 129 ppb inorganic arsenic.³⁷

Hain Celestial, FDA Testing Result Investigation, August 1, 2019 (Excerpted Entries)³⁸

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN 12216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

The Subcommittee's review of the ingredient test results reveals that Hain routinely used ingredients with high levels of arsenic. Hain used brown rice flour that had tested at 309 ppb arsenic.³⁹ Hain likewise used a vitamin pre-mix containing 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.⁴⁰ The testing data shows that Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its already-dangerously-high internal standard for most ingredients.⁴¹

Hain, Raw Material Pre-Shipment Test Data History (Excerpted Entries)⁴²

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Jun/19/2019	Org Brown Rice Flour	Deviation Approved	100	309
Nov/26/2019	Vitamin Pre-Mix	Deviation Approved	100	223
Jul/10/2018	Org Whole Raisins	Accepted	100	200
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Dec/14/2017	Org Spelt Flour	Accepted	100	190
Jan/8/2018	Organic Barley Malt Extract	Accepted	100	180
Dec/5/2017	Org Yellow Split Pea Powder	Accepted	100	160
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150
Oct/3/2017	Org Brown Rice Flour	Accepted	100	140
Sep/4/2019	Org Brown Rice Flour	Deviation Approved	100	134
Dec/5/2017	Org Butternut Squash Puree	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	130

³⁷ Hain, *PowerPoint Presentation to FDA: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

³⁸ *Id.*

³⁹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

Oct/31/2017	Org Brown Rice Flour	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	127
Oct/31/2017	Org Brown Rice Flour	Accepted	100	126
Dec/13/2017	Org Blueberry Puree	Accepted	100	120
Dec/27/2017	Org Barley Flour	Accepted	100	120
Oct/31/2017	Org Brown Rice Flour	Accepted	100	119
Nov/29/2017	Org Blueberry Puree	Accepted	100	110
Nov/3/2017	Org Cinnamon Powder	Accepted	100	110
Jul/11/2019	Org Brown Rice Flour	Accepted	100	101

3. Beech-Nut used ingredients in its baby foods with as much at 913.4 ppb arsenic; Beech-Nut routinely used ingredients that exceeded 300 ppb total arsenic; Beech-Nut unnecessarily uses high-arsenic additives to address issues like “crumb softness.”

Beech-Nut only tested arsenic content in its ingredients, not its final product. The Subcommittee has determined that Beech-Nut used ingredients containing as much as 913.4 ppb arsenic.⁴³ Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic.⁴⁴ And it used at least 45 ingredients containing over 100 ppb arsenic.

Beech-Nut, Raw Material Heavy Metal Testing (Excerpted Entries)⁴⁵

Date	Commodity	Arsenic Result (ppb)	Spec.	Acceptance (Y/N)
9/19/2018	Amylase	913.40	N/A	Y
4/26/2018	Amylase	741.10	N/A	Y
10/7/2017	BAN 800	710.90	<3000	Y
11/29/2017	Alpha Amylase	679.00	N/A	Y
10/12/2017	Amylase	645.10	N/A	Y
8/20/2019	Sebamyl 100	583.60	N/A	Y
3/6/2018	Org. Rice Flour	570.00	≤100(inorg)	Y
6/7/2019	Enzyme	499.30	N/A	Y
12/20/2017	BAN 800	465.20	<3000	Y
1/14/2019	Enzyme	442.30	N/A	Y
10/23/2017	BAN 800	401.40	<3000	Y

⁴³ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁴⁴ *Id.*

⁴⁵ *Id.*

2/19/2018	BAN 800	382.00	<3000	Y
6/12/2018	Ban 800	353.80	<3000	Y
5/21/2018	Org. Cumin	322.70	≤1000	Y
4/13/2018	Org. Rice	237.40	≤100(inorg)	Y
4/12/2018	Rice Flour	170.00	≤100(inorg)	Y
4/6/2018	Rice Flour	170.00	≤100(inorg)	Y
7/14/2017	Org. Cumin	168.50	≤1000	y
7/31/2018	rice flour	162.00	≤100(inorg)	Y
2/28/2018	Rice Flour	161.00	≤100(inorg)	y
3/30/2017	Cumin	160.50	≤1000	Y
3/27/2018	Rice Flour	160.00	≤100(inorg)	Y
5/30/2018	Rice Flour	160.00	≤100(inorg)	Y
6/12/2018	Rice Flour	160.00	≤100(inorg)	Y
7/20/2018	Rice Flour	160.00	≤100(inorg)	Y
10/11/2016	Oregano	158.10	<1000	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
2/15/2018	Rice Flour	150.00	≤100(inorg)	Y
5/31/2018	Rice Flour	150.00	≤100(inorg)	Y
2/22/2018	Rice Flour	140.00	≤100(inorg)	Y
1/6/2018	Rice Flour	140.00	≤100(inorg)	Y
4/6/2018	Rice Flour	140.00	≤100(inorg)	Y
9/4/2019	Org. rice	132.30	≤200	Y
11/3/2017	Org.Cumin	130.20	≤1000	Y
2/15/2018	Rice Flour	130.00	≤100(inorg)	Y
2/5/2018	Rice Flour	130.00	≤100(inorg)	Y
2/8/2018	Rice Flour	130.00	≤100(inorg)	Y
1/5/2018	Rice Flour	122.30	≤100(inorg)	Y
1/5/2018	Rice Flour	120.80	≤100(inorg)	Y
2/8/2018	Rice Flour	120.00	≤100(inorg)	Y
1/18/2017	Org.Rice	110.00	≤200	Y
5/8/2018	Rice Flour	110.00	≤100(inorg)	Y
5/17/2017	Rice	110.00	≤200	Y
2/6/2017	Vitamin Mix	106.90	<3000	Y

The six Beech-Nut ingredients with the highest arsenic levels—Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly “[i]ncreases crumb softness” in baked goods.⁴⁶ Amylase is an

⁴⁶ Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018) (online at www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf).

enzyme that is “used in bread-making as an additive to improve the conversion of complex sugars into simple sugars that yeast are then able to feed on and produce alcohol and CO₂.”⁴⁷

4. Gerber used 67 batches of rice flour that had more than 90 ppb inorganic arsenic.

Gerber did not provide inorganic arsenic results for all of its ingredients. However, test results for conventional rice flour revealed that Gerber routinely used flour with over 90 ppb inorganic arsenic.⁴⁸ Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.

Gerber Products Company Test Results (Excerpted Entries)⁴⁹

Year	Ingredient	Total Arsenic (ppb)	Inorganic Arsenic (ppb)
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96

⁴⁷ ChefSteps, *Amylase* (online at www.chefsteps.com/ingredients/amylase) (accessed Jan. 26, 2021).

⁴⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁴⁹ *Id.*

2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	95	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	94	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	121	93
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	92	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92

2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91

B. Lead

There is a growing consensus among health experts that lead levels in baby foods should not exceed 1 ppb. The American Academy for Pediatrics, the Environmental Defense Fund, and Consumer Reports have all, in some form, called for a 1 ppb level in food and drinks that babies and children consume.⁵⁰ Healthy Babies Bright Futures has called for a goal of no measurable amount of lead in baby food.⁵¹

There is no federal standard for lead in baby food. However, FDA has set a 5 ppb lead standard for bottled water, WHO has set 10 ppb lead as a provisional guideline for drinking water, and EPA has set an action level of 15 ppb for lead in drinking water. FDA has also set standards for lead in juice (50 ppb) and candy (100 ppb). The European Union has set the maximum lead level in infant formula to 20 ppb.⁵²

⁵⁰ American Academy of Pediatrics, *Prevention of Childhood Lead Toxicity* (May 5, 2016) (online at <https://pediatrics.aappublications.org/content/pediatrics/early/2016/06/16/peds.2016-1493.full.pdf>); Environmental Defense Fund, *Lead in Food: A Hidden Health Threat* (June 15, 2017) (online at www.edf.org/sites/default/files/edf_lead_food_report_final.pdf); Consumer Reports, *Consumer Reports Letter to FDA on Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>).

⁵¹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁵² World Health Organization, *Lead in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf); Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/lead-and-copper-rule) (accessed Jan. 26, 2021); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

Proposed and Existing Lead Standards

Group or Agency	Standard
Environmental Defense Fund	1 ppb, especially for baby food
Consumer Reports	1 ppb in fruit juices
American Academy of Pediatrics (AAP)	1 ppb for water fountains in schools
FDA	5 ppb for bottled water
World Health Organization	10 ppb provisional guideline
EPA	15 ppb for drinking water (action level)
European Union (EU)	20 ppb for “infant formulae and follow-on formulae”
FDA	50 ppb for juice
	100 ppb for candy

The Subcommittee’s investigation has found that baby food manufacturers are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Internal testing data from Gerber, Nurture, Beech-Nut, and Hain demonstrate that all four companies sold products or used ingredients with significant amounts of lead. Only Nurture routinely tested its finished product for lead. Hain, Beech-Nut, and Gerber did not test their finished products, only their ingredients. All companies, whether they test their final products or merely their ingredients, sold baby foods even when they or their ingredients contained unsafe levels of lead.

1. Nurture (HappyBABY) sold finished baby food products after testing confirmed they contained as much as 641 ppb lead, over six times its already-dangerously-high internal standard.

Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead.⁵³ Nurture also sold five other products after they tested over 50 ppb lead.⁵⁴

⁵³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁵⁴ *Id.*

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁵⁵

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition										
Blueberry Purple Carrot	Baby 7+ Months	10/25/2017	Lead	100	641	ppb	01/27/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Lead	100	580	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Apple Spinach Kiwi Cre	Baby 7+ Months	8/4/2018	Lead	100	86	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Blueberry Beet Rice Ca	Baby 7+ Months	5/22/2018	Lead	100	61	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Pea Spinach Teether	Baby 7+ Months	10/24/2019	Lead	100	55	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Pea Spinach Teether	Baby 7+ Months	05/07/2019	Lead	100	50	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										

Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding the lenient EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.⁵⁶ It is not clear that even one of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

2. **Beech-Nut used ingredients containing as much as 886.9 ppb lead; Beech-Nut routinely used ingredients with high lead content, including 483 ingredients that contained over 5 ppb lead, 89 ingredients that contained over 15 ppb lead, and 57 ingredients that contained over 20 ppb lead.**

Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance, Beech-Nut used cinnamon that contained 886.9 ppb lead.⁵⁷

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entry)⁵⁸

Date	Commodity	Preshipment Lot	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	cinnamon	762	18.8	≤1000	344.5	≤1000	886.9	≤1000	Y

Beech-Nut tested and used 57 ingredients that contained over 20 ppb lead, the EU's lax standard for lead in infant formula. Beech-Nut accepted 89 ingredients that tested at or over 15 ppb lead, EPA's action level for drinking water, and 483 ingredients that tested at or over 5 ppb lead, FDA's standard for lead in bottled water.⁵⁹

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁵⁸ *Id.*

⁵⁹ *Id.*

*Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)*⁶⁰

Date	Commodity	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	886.9	≤1000	Y
5/21/2018	Org. Cumin	644.9	≤1000	Y
8/11/2017	Org. Coriander	603.5	<1000	Y
10/11/2016	Oregano	570.4	<1000	Y
7/14/2017	Org. Cumin	231.2	≤1000	y
5/31/2017	Cinnamon	203.9	≤1000	Y
3/30/2017	Cumin	177.7	≤1000	Y
11/3/2017	Org. Cumin	167.7	≤1000	Y
12/5/2017	Org. Cinnamon	126.2	≤1000	Y
11/29/2017	Alpha Amylase	114.5	<300	Y
9/19/2018	Amylase	108.8	<300	Y
7/11/2017	Org. Lemon	102	≤160	Y
7/8/2019	Org. Cinnamon	100	≤1000	Y
7/12/2019	Org. Cinnamon	100	≤1000	Y
10/12/2017	Amylase	95.8	<300	Y
4/26/2018	Amylase	91	<300	Y
4/12/2017	Turmeric	76.3	≤1000	Y
8/27/2018	Sunflower Lecithin	71.6	≤100	Y
8/3/2017	Org. Lemon	63.7	≤160	Y

⁶⁰ *Id.*

4/11/2018	Org. Cinnamon	59	≤1000	Y
11/2/2018	S. Potato	55.3	≤15	Y
4/21/2017	Sunflower Lecithin	54.9	≤100	Y
8/15/2018	Quinoa Flour	51.6	<75	Y
11/2/2018	S. Potato	50.1	≤15	Y
10/25/2016	Lemon	47.5	≤160	Y
1/14/2019	Enzyme	47.3	<300	Y
5/31/2018	Prune Puree	41.5	≤40	Y - ER
11/6/2018	S. Potato	40.3	≤15	Y
9/29/2017	Org. Turmeric	39.3	≤1000	Y
9/13/2019	Org. Cinnamon	37.8	≤1000	Y
8/11/2017	Org. Cinnamon	36.7	≤1000	y
11/6/2018	S. Potato	35.2	≤15	Y
11/2/2018	S. Potato	34.9	≤15	Y
10/10/2018	Dehydrated Potato	32.4	<75	Y - ER
8/2/2018	Mango	32.3	≤20	Y
11/2/2018	S. Potato	31.8	≤15	Y
6/11/2018	Sunflower Lecithin	31.7	≤100	Y
8/6/2018	Prune	31.1	≤40	
8/20/2019	Sebamyl 100	30.6	<300	Y
3/19/2018	Org. Prune	30	≤40	Y
9/20/2016	Apricot	28	≤20	Y - ER
2/13/2019	Org. Prune	27.9	≤40	Y - ER

6/7/2019	Enzyme	26.3	<300	Y
6/19/2018	Org. Quinoa Flour	25.3	<75	Y - ER
2/6/2017	Vitamin Mix	24.6	<10	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
2/1/2019	Blueberry	22.7	<25	Y
11/6/2018	S. Potato	22	≤15	Y
3/18/2019	Org. Pears	21.7	<10	
6/14/2019	Sunflower Lecithin	21	≤100	Y
3/20/2018	Carrots	20	<25	Y - ER
3/20/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/16/2017	Sunflower Lecithin	20	≤100	Y
3/1/2019	Org. Cinnamon	20	≤1000	Y

3. Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead; Hain consistently used baby food ingredients with high lead content, including 88 ingredients that tested over 20 ppb lead and six ingredients that tested over 200 ppb lead.

Hain used an ingredient called vitamin pre-mix in its baby food that contained as much as 352 ppb lead.⁶¹

⁶¹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)⁶²

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Hain used six ingredients that tested above 200 ppb lead. Hain used 88 ingredients with lead levels at or over 20 ppb—the EU's standard for lead in infant formula. Hain accepted 115 ingredients that registered at or over 15 ppb—EPA's action level for drinking water. And at least 27% of Hain ingredients tested at or over 5 ppb lead, FDA's standard for lead in bottled water. None of the test results showed an ingredient below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

Hain's Raw Material Pre-Shipment Test Data History (Excepted Entries for Ingredients Above 200 ppb Lead)⁶³

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	60.5	100	352
Jan/19/2018	Grain Millers	471138	Org Whole Wheat Fine Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	160	100	250
Dec/28/2017	Grain Millers	471011	Org Quick Oats	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	<100	100	230
Dec/27/2017	Grain Millers	55300	Org Barley Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	120	100	<100	100	230
Nov/3/2017	Starwest Botanicals	40500	Org Cinnamon Powder	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	110	100	200	100	230
Jan/22/2018	Jewel Date	14300	Org Date Paste	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	190	100	220

4. Gerber used ingredients that tested as high as 48 ppb lead; and routinely accepted ingredients containing over 20 ppb lead.

Gerber produced limited lead testing results. The results for its sweet potatoes and juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead. Gerber also used twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.⁶⁴

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

Gerber Products Company Test Results (Excerpted Entries)⁶⁵

Year	Ingredient	Lead Level (ppb)
2017	Conventional	48
2017	Organic	35
2017	Organic	34
2017	Organic	34
2018	Conventional	34
2019	Conventional	34
2019	Conventional	34
2018	Organic	25
2019	Organic	25
2018	Organic	22
2018	Organic	22
2018	Organic	21
2019	Conventional	21

The average amount of lead in Gerber’s tested juice concentrates was 11.2 ppb—more than FDA’s limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports’ recommended limit for fruit juices.

Gerber Products Company Test Results (Excerpted Entries)⁶⁶

GERBER Products Company Test Results			Confidential Business Information
			19-Dec-19
Juice Concentrate Ingredients (Lead Results)			
Year	Ingredient		Lead (ppb)
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	29
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	26
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	25

⁶⁵ *Id.*

⁶⁶ *Id.*

C. Cadmium

Outside the context of baby food, some regulation has taken action against cadmium. For example, EPA has a limit of 5 ppb in drinking water, and FDA has set a limit of 5 ppb in bottled water.⁶⁷ These standards approach WHO's 3 ppb limit for cadmium in drinking water.⁶⁸

Groups like Healthy Babies Bright Futures have set a goal of no measurable amount of cadmium in baby food.⁶⁹ Consumer Reports has called for a limit of 1 ppb cadmium in fruit juices.⁷⁰ And the EU has set a limit ranging from 5–20 ppb cadmium for infant formula.

The Subcommittee found that baby food manufacturers sold many products with much higher cadmium content.

Proposed and Existing Cadmium Standards

Group or Agency	Standard
Consumer Reports	1 ppb in all fruit juices
World Health Organization	3 ppb for drinking water
EPA	5 ppb for drinking water
FDA	5 ppb for drinking water
European Union (EU)	5-20 ppb for infant formulae

1. **Beech-Nut used ingredients in its baby food containing up to 344.55 ppb cadmium; 105 Beech-Nut ingredients tested over 20 ppb cadmium.**

Beech-Nut used twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium.⁷¹ That is more than 17 times higher than the EU's lax

⁶⁷ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

⁶⁸ World Health Organization, *Cadmium in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1).

⁶⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁷⁰ Consumer Reports, *Consumer Reports Letter To FDA On Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

⁷¹ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

upper limit on cadmium in baby food. At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb cadmium—the EU’s lax infant formula upper limit.⁷²

Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)⁷³

Date	Commodity	Cadmium Result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	344.50	≤1000	Y
4/11/2018	Org. Cinnamon	225.10	≤1000	Y
5/31/2017	Cinnamon	194.30	≤1000	Y
6/8/2018	Org. Garlic	186.00	≤1000	Y
8/11/2017	Org. Cinnamon	178.20	≤1000	y
10/11/2016	Oregano	176.50	<1000	Y
12/5/2017	Org. Cinnamon	163.40	≤1000	Y
11/29/2017	Dehydrated Potato	148.40	<90	Y - ER
10/10/2018	Dehydrated Potato	146.00	<90	Y
10/10/2018	Dehydrated Potato	143.50	<90	Y - ER
7/10/2019	Spinach Puree	143.00	<180	Y
7/2/2018	Fresh Spinach	142.30	<180	Y
7/8/2019	Org. Cinnamon	140.00	≤1000	Y
7/12/2019	Org. Cinnamon	140.00	≤1000	Y
3/1/2019	Org. Cinnamon	120.00	≤1000	Y
11/29/2017	Dehydrated Potato	119.60	<90	Y - ER
9/13/2019	Org. Cinnamon	117.30	≤1000	Y
7/15/2019	Spinach	117.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y

2. Hain (Earth’s Best Organic) used ingredients in its baby food containing up to 260 ppb cadmium; 102 Hain ingredients tested over 20 ppb cadmium.

Hain used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.⁷⁴ That is thirteen times the EU’s lax upper limit on cadmium in baby food. Hain tested and used 102 ingredients that registered at or above 20 ppb cadmium—the EU’s lax upper limit.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)⁷⁵

Lab Results Date	Products Description	Status	Cadmium Spec. limit (ppb)	Cadmium Result (ppb)
Jan/19/2018	Org Barley Flour	Accepted	100	260
Jan/22/2018	IQF Org Chopped Broccoli	Accepted	100	250
Jan/23/2018	Org Date Paste	Accepted	100	220
Nov/3/2017	Org Cinnamon Powder	Accepted	100	200
Aug/21/2017	Org Brown Flax Milled	Accepted	100	190
Jan/22/2018	Org Date Paste	Accepted	100	190
Jan/18/2018	Org Yellow Papaya Puree	Accepted	100	170
Jan/19/2018	Org Whole Wheat Fine Flour	Accepted	100	160
Aug/17/2017	Org Red Lentils	Accepted	100	130
Jan/15/2018	Org Oat Flakes	Accepted	100	130
Jun/13/2018	Org Brown Flax Milled	Accepted	100	121
Jan/12/2018	Org Barley Flour	Accepted	100	110
Jun/25/2018	Org Oat Flour	Accepted	100	102
Feb/19/2019	Org Cinnamon Powder	Deviation Approved	100	102

3. Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium, the EPA's limit for drinking water.

Nurture sold multi-grain cereal with 49 ppb cadmium. Nurture sold another 125 products that tested over 5 ppb, which is the EPA's limit for drinking water.⁷⁶

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁷⁷

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test	Disposition
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Cadmium	50	49	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	1/18/2019	Cadmium	50	36	ppb	12/06/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	12/4/2020	Cadmium	50	35	ppb	10/09/19	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	11/10/2019	Cadmium	50	31	ppb	10/23/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	11/10/2019	Cadmium	50	30	ppb	10/31/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁷⁵ *Id.*

⁷⁶ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁷⁷ *Id.*

4. Gerber used carrots containing as much as 87 ppb cadmium; 75% of Gerber's carrots contain cadmium in excess of 5 ppb.

Gerber does not test all its ingredients for cadmium. Of those it does test, it accepts ingredients with high levels of cadmium. Gerber used multiple batches of carrots containing as much as 87 ppb cadmium, and 75% of the carrots Gerber used had more than 5 ppb cadmium—the EPA's drinking water standard.⁷⁸

Gerber Products Company Test Results (Excerpted Entries)⁷⁹

Year	Ingredient	Supplier	Arsenic (ppb)	Cadmium (ppb)	Mercury (ppb)	Lead (ppb)
2018	Conventional	Supplier 1		87		
2018	Conventional	Supplier 4		53		
2019	Conventional	Supplier 4		42		
2017	Conventional	Supplier 1	<2	40	<1	4

D. Mercury

Outside the context of baby food, some regulation has taken action against mercury. EPA, for example, has capped mercury in drinking water at 2 ppb.⁸⁰ Consumer advocates urge even stricter standards for baby food. For example, Health Babies Bright Futures has called for a goal of no measurable amount of mercury in baby food.⁸¹

1. Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.

Nurture sold a finished baby food product that contained 10 ppb mercury, and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA's 2 ppb standard for drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.⁸²

⁷⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁷⁹ *Id.*

⁸⁰ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

⁸¹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁸² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁸³

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition
Brown Rice Cereal Canister	Baby 6+ Months	08/16/2019	Mercury	10	10	ppb	08/20/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana Sweet Potato Tee	Baby 7+ Months	6/9/2019	Mercury	10	9.8	ppb	04/16/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Brown Rice Cereal Canister	Baby 6+ Months	04/17/2019	Mercury	10	7.3	ppb	12/04/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

2. Beech-Nut and Hain (Earth's Best Organic) did not even test for mercury in baby food; Gerber barely tests for it.

From the documents produced to this Subcommittee, it appears that neither Beech-Nut nor Hain tests their ingredients or their finished products for mercury.

Gerber only tests certain ingredients for mercury. Of the test results they presented to the Subcommittee, they only tested carrots, sweet potatoes, and lemon juice concentrate.

III. INDUSTRY SELF-REGULATION FAILS TO PROTECT CONSUMERS: NURTURE, BEECH-NUT, HAIN, AND GERBER SET THEIR OWN DANGEROUSLY HIGH INTERNAL STANDARDS FOR TOXIC HEAVY METAL LEVELS AND ROUTINELY IGNORED THEM TO SELL PRODUCTS WITH HIGHER HEAVY METAL LEVELS.

Baby food manufacturers are free to set their own internal standards for toxic heavy metal content of their products. They have set those standards at dangerously high levels and have often sold foods that exceed even those levels.

A. Nurture (HappyBABY) sets high internal standards and regularly exceeds them. Nurture admits that its toxic heavy metal testing is not for safety—it sells all products tested, regardless of its toxic heavy metal content. FDA has finalized only one standard—100 ppb inorganic arsenic in infant rice cereal—Nurture has ignored it, setting its internal standard for that product at 115 ppb.

Nurture created internal standards but did not follow them. Nurture describes these standards as “goal thresholds” that “are not used to make product disposition decisions and are not a pre-condition to product release.”⁸⁴ Instead, its testing regime is limited to monitoring the supply chain. Nurture's thresholds are not actually used to prevent products that contain high levels of toxic heavy metals from being sold.⁸⁵

⁸³ *Id.*

⁸⁴ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁵ *Id.*

Nurture does not even claim to be testing for safety—it made clear in its letter response to this Subcommittee that all products will be sold regardless of testing result: **“our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into commerce.”**⁸⁶

Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold every product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards.

As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.⁸⁷

Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Nurture’s standards “are not used to make product disposition decisions and are not a pre-condition to product release.” Instead, their testing regime is limited to monitoring the supply chain.⁸⁸

Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁸⁹

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	ppb	11/01/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	3/16/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	11/16/2018	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Purple Carrot & Blueberry Puffs	Baby 7+ Months	2/15/2019	Inorganic Arsenic	100	150	ppb	11/17/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Sweet Potato & Carrot Puffs	Baby 7+ Months	1/19/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁸⁶ *Id.*

⁸⁷ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁸⁸ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁹ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Further, Nurture appears to have misled the Subcommittee about its testing standards. As seen from Nurture's goal thresholds pictured below, Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.⁹⁰ However, in the test results that Nurture provided to this Subcommittee, it was still using 100 ppb as an internal guideline after January 2019.

This image is from Nurture's December 18, 2019, response to the Subcommittee, stating that after January of 2019, its lead threshold was 50 ppb in all baby food products:⁹¹

All of our specific goal thresholds for the referenced contaminants⁸ are set forth in the chart below.

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb
Cereals	Lead	As Consumed	50*	ppb
Cereals	Mercury	As Consumed	10	ppb
Wet Foods	Cadmium	As Consumed	50	ppb
Wet Foods	Inorganic Arsenic	As Sold	100	ppb
Wet Foods	Lead	As Consumed	50*	ppb
Wet Foods	Mercury	As Consumed	10	ppb

*Threshold lowered from 100ppb to 50ppb in January, 2019.

However, the chart below appears to show that after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a “Goal Threshold” of 100 ppb for 53 baby food products. The fact that Nurture appears to have continued using a higher standard up to nine months after it claimed to the Subcommittee to have lowered the threshold casts serious doubt on Nurture's candor in this matter.

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁹²

⁹⁰ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹¹ *Id.*

⁹² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Product Name	Parameter	Goal Threshold	Result	Unit	Date of Test Report
Blueberry Beet Rice Cakes	Lead	100	<4.0	ppb	10/14/19
Stage 3 Root Vegetable and Turkey	Lead	100	<4.0	ppb	10/11/19
Apple & Broccoli Puffs	Lead	100	5.8	ppb	10/10/19
Apple Cinnamon Oat Jar	Lead	100	<4.0	ppb	10/09/19
Apple Spinach Jar	Lead	100	<4.0	ppb	10/09/19
Kale & Spinach Puffs	Lead	100	9.7	ppb	10/09/19
Apple Mango Beet	Lead	100	<4.0	ppb	08/22/19
Pear Prune Jar	Lead	100	<4.0	ppb	08/22/19
Apple Spinach Pea & Kiwi	Lead	100	43	ppb	08/22/19
Pea Spinach Teether	Lead	100	18	ppb	08/16/19
Strawberry Yogis	Lead	100	<4.0	ppb	08/13/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	07/25/19
Banana & Pumpkin Puffs	Lead	100	6.2	ppb	07/25/19
Apples Blueberries & Oats	Lead	100	<4.0	ppb	07/24/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/24/19
Green Beans Jar	Lead	100	<4.0	ppb	07/24/19
Pears Mangoes & Spinach	Lead	100	<4.0	ppb	07/24/19
Carrots	Lead	100	<4.0	ppb	07/20/19
Pea Spinach Teether	Lead	100	23	ppb	07/11/19
Apple & Broccoli Puffs	Lead	100	11	ppb	07/11/19
Kale & Spinach Puffs	Lead	100	11	ppb	07/11/19
Mangoes	Lead	100	<4.0	ppb	07/03/19
Sweet Potatoes Jar	Lead	100	<4.0	ppb	07/03/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/02/19
Harvest Vegetables & Chicken	Lead	100	<4.0	ppb	07/02/19
Apple Rice Cakes	Lead	100	7.2	ppb	07/02/19
Blueberry Purple Carrot Greek Yogis	Lead	100	4.3	ppb	07/02/19
Apple & Broccoli Puffs	Lead	100	9.9	ppb	05/30/19
Strawberry & Beet Puffs	Lead	100	10	ppb	05/22/19
Apples & Spinach	Lead	100	<4.0	ppb	05/15/19
Clearly Crafted Apple Guava Beet	Lead	100	<4.0	ppb	05/10/19
Sweet Potato Jar	Lead	100	<4.0	ppb	05/10/19
Banana & Pumpkin Puffs	Lead	100	13	ppb	04/24/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	04/24/19
Apple Pumpkin Carrots	Lead	100	<4.0	ppb	04/12/19
Pea Spinach Teether	Lead	100	23	ppb	04/12/19
Multi-Grain Cereal Canister	Lead	100	5.2	ppb	04/12/19
Carrots	Lead	100	<4.0	ppb	04/11/19
Sweet Potato Jar	Lead	100	<4.0	ppb	04/11/19
Apple Spinach Pea & Kiwi	Lead	100	34	ppb	03/29/19
Strawberry & Beet Puffs	Lead	100	7.8	ppb	03/21/19

Banana & Pumpkin Puffs	Lead	100	5.5	ppb	03/21/19
CC Oatmeal Cereal	Lead	100	<4.0	ppb	03/18/19
Carrots & Peas	Lead	100	<4.0	ppb	03/13/19
CC Prunes	Lead	100	<4.0	ppb	03/13/19
Pears & Kale Jar	Lead	100	<4.0	ppb	03/13/19
Vegetable & Beef Medley	Lead	100	<4.0	ppb	03/07/19
Banana Sweet Potato Teether	Lead	100	12	ppb	02/19/19
Banana & Pumpkin Puffs	Lead	100	11	ppb	02/19/19
Blueberry Purple Carrot Teether	Lead	100	10	ppb	02/19/19
Mangoes	Lead	100	<4.0	ppb	02/13/19
Apple Mango Beet	Lead	100	<4.0	ppb	02/12/19
Strawberry Banana Greek Yogis	Lead	100	<4.0	ppb	02/12/19

Nurture has also ignored the only final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.⁹³

*Excerpt of December 18, 2019, Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi*⁹⁴

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb

B. Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in dangerous additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.

Beech-Nut has set an internal specification limit (listed in the chart below as “spec.”) of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.⁹⁵ As a result of

⁹³ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹⁴ *Id.*

⁹⁵ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

adopting this high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.⁹⁶ Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.⁹⁷ These far surpass any existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee's inquiry.

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)⁹⁸

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
12/20/2017	BAN 800	786	465.20	<3000	6.30	<500	<58	<5000	Y
1/23/2019	ascorbic acid	80	<5	<3000	<1	<3000	<5	<3000	Y
10/7/2017	BAN 800	673	710.90	<3000	8.30	<500	<5	<5000	Y
10/23/2017	BAN 800	712	401.40	<3000	6.10	<500	<5	<5000	Y
2/19/2018	BAN 800	120	382.00	<3000	<5	<500	<5	<5000	Y
6/12/2018	Ban 800	292	353.80	<3000	<5	<500	<5	<5000	Y
3/12/2018	BAN 800	164	29.70	<3000	<5	<500	<5	<5000	Y
2/6/2017	Vitamin Mix	76	106.90	<3000	60.30	<3000	24.6	<10	Y
1/31/2017	Vitamin Mix	72	89.40	<3000	48.20	<3000	18	≤20	Y
10/10/2019	BAN 800	680	91.10	<3000	28.40	<500	7.5	<5000	Y
12/5/2018	ascorbic acid	1084	<5	<3000	<5	<3000	6	<3000	Y
9/4/2019	BAN 800	442	59.70	<3000	11.00	<500	5.8	<5000	Y

Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient.⁹⁹

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)¹⁰⁰

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
1/11/2018	Oat Flour	38	47.00	≤40	21.80	≤20	<5	≤20	Y
1/16/2018	Coarse Oat Flour	45	45.60	≤40	20.70	≤20	<5	≤20	Y
6/22/2018	Org. Oat Flour	299	24.00	≤40	20.80	≤20	<5	≤20	Y
7/5/2018	oat flour	299	24.00	≤40	20.80	≤20	<5	≤20	
3/13/2018	Coarse Oat Flour	168	23.40	≤40	20.70	≤20	<5	≤20	Y
10/1/2019	Oat Flour	645	20.90	≤40	20.90	≤20	<5	≤20	Y
9/13/2019	Oat Flour	554	18.20	≤40	22.30	≤20	<5	≤20	Y
10/10/2018	Dehydrated Potato	816	11.30	<75	143.50	<90	32.4	<75	Y - ER
11/29/2017	Dehydrated Potato	760	9.30	<75	148.40	<90	10.1	<75	Y - ER
1/30/2018	Org. Oat Flour	73	8.50	≤40	21.70	≤20	<5	≤20	Y - ER
11/29/2017	Dehydrated Potato	749	7.60	<75	119.60	<90	<5	<75	Y - ER

Beech-Nut's explanation of why it accepted products over its own internal limits was that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's allowable limits...."¹⁰¹ However, as the cadmium examples show, Beech-Nut accepted certain ingredients in spite of their own testing results which showed that they contained over 20% more cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.¹⁰² Beech-Nut did not offer any explanation.

C. Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. Hain justified deviations above its ingredient testing standards based on "theoretical calculations," even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

Hain set an internal standard of 200 ppb arsenic for 12 ingredients, most of which were different kinds of flours. By setting this high internal standard, Hain justified accepting wheat flour and rice that contained 200 and 150 ppb arsenic.¹⁰³

¹⁰⁰ *Id.*

¹⁰¹ Letter from the President and Chief Executive Officer of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf).

¹⁰² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

¹⁰³ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁴

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Aug/3/2017	Org Kamut Flour	Accepted	200	<100
Aug/3/2017	Org Spelt Flour	Accepted	200	<100
Jul/6/2017	Org Yellow Split Pea Powder	Accepted	200	<100
Jul/5/2017	Org Quinoa Flour	Accepted	200	<100
May/26/2017	Org Soft White Wheat Flour	Accepted	200	<100
Aug/1/2017	Org Fiber Oat	Accepted	200	<100
Sep/25/2017	Org Quinoa Flour	Accepted	200	<100
Sep/12/2017	Org Spelt Flour	Accepted	200	<100
Aug/4/2017	Org Spelt Flour	Accepted	200	<100
Jul/19/2017	Org Green Lentil Flour	Accepted	200	<100
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150

Similarly, Hain set an internal limit of 200 ppb for lead in five ingredients—forty times higher than FDA's guidance for bottled water. By doing so, Hain justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead.¹⁰⁵

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁶

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Lead Spec Limit (ppb)	Lead Result (ppb)
Aug/3/2017	Montana Flour & Grains	5303053	Org Kamut Flour	Accepted		Deibel	As consumed	200	<100
Jul/19/2017	Firebird Artisan Mills	57200	Org Green Lentil Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	110
Aug/2/2017	Grain Millers	5308029	Org Brown Flax Milled	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	<100
Jul/5/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted		Deibel	As consumed	200	<100
Sep/29/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted	spec for lead was 200ppb	Deibel	As consumed	200	120

¹⁰⁴ *Id.*¹⁰⁵ *Id.*¹⁰⁶ *Id.*

Hain used four products that surpassed its internal toxic heavy metal limits. For example, it accepted cinnamon that contained 102 ppb cadmium, vitamin pre-mix that had 223 ppb arsenic and 353 ppb lead, and two rice flours that had 134 and 309 ppb arsenic.¹⁰⁷

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)¹⁰⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Feb/19/2019	Red Ape Cinnamon	40500	Org Cinnamon Powder	Deviation Approved	Accepted on deviation 20190045	Deibel	As Purchased	100	20	100	102	100	40
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C ovanco	As Purchased	100	223	100	60.5	100	352
Jun/19/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 20190127	Eurofins/C ovanco	As Purchased	100	309	100	23	100	<10
Sep/4/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 2019030 and 20190234	Eurofins/C ovanco	As Purchased	100	134	100	12.8	100	5

Hain justified these variations by claiming that the “theoretical” final goods will not surpass its internal limits. For example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.¹⁰⁹

Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)¹¹⁰

Ingredient Exp. Date		
Lot Code	19090122P	
Specification	Arsenic: 100 ppb Lead: 100 ppb	Arsenic: 223 ppb Lead: 352 ppb
Highest Percentage in Finished Good(s)	2.08%	

Despite having dangerously high levels of toxic heavy metals, Hain approved the use of this vitamin pre-mix based on a “theoretical” calculation of toxic heavy metals in the final good.¹¹¹

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf).

¹¹⁰ *Id.*

¹¹¹ *Id.*

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹²

QUALITY & FOOD SAFETY REVIEW		
Reviewed Date	11/26/2019	Select one: <input checked="" type="radio"/> Approved <input type="radio"/> Rejected <input type="radio"/> Revisions Requested
Reviewed By	[REDACTED]	
Comments	Vitamin premix is used at 2.08% in the rice cereal finished good C90001. Upon theoretical calculations including the 10% variation, the arsenic and lead levels in the finished product are below 100 ppb. Attached calculations.	

To calculate the estimated quantity of lead and arsenic in the finished good, Hain considered the percentage of rice flour and vitamin pre-mix in the finished goods, and their projected amounts of arsenic and lead. Ultimately, Hain predicted that the finished good would have roughly 85 ppb arsenic and 25 ppb lead.¹¹³

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹⁴

Item	Lot Code	Heavy Metal	Test Value (ppb)	% in formula	Hypothetical Level in finished product (ppb)	
Rice Flour	B160007680	Inorganic Arsenic	81.9	97.8	80.0982	
		Lead	17.6	97.8	17.2128	
		Cadmium	18.6	97.8	18.1908	
Vitamin Premix	19090122P	Inorganic Arsenic	223	2.08	4.6384	
		Lead	352	2.08	7.3216	
		Cadmium	60.5	2.08	1.2584	
			Theoretical Arsenic		84.7366	93.21026
			Theoretical Lead		24.5344	26.98784
			Theoretical Cadmium		19.4492	21.39412

However, it is not clear that Hain ever tested the finished good. Hain appears to have used this vitamin pre-mix with dangerously high levels of toxic heavy metals without ever confirming the finished good was actually safe to consume.

Hain made this decision four months *after* it had made a secret presentation to FDA admitting that heavily tainted vitamin premix caused dangerous levels of arsenic in its finished

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

products, which initially went undetected because Hain did not test its finished products.¹¹⁵ Hain made no effort to correct the problem. *Note: Full discussion of Hain's secret presentation to FDA appears in Section V., Parts D. and E., below.*

IV. WALMART, SPROUT ORGANIC FOODS, AND CAMPBELL REFUSED TO COOPERATE WITH THE SUBCOMMITTEE'S INVESTIGATION

Nurture, Beech-Nut, Hain, and Gerber cooperated with the Subcommittee's investigation, despite the fact that doing so exposed their reckless disregard for the health of babies. With that in mind, the Subcommittee questions why Walmart (Parent's Choice), Sprout Organic Foods, and Campbell (Plum Organics) would refuse to comply with the investigation. None of them produced testing results or specific testing standards and Sprout never even responded to the Subcommittee's repeated inquiries. The Subcommittee is greatly concerned that these companies might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

A. Walmart (Parent's Choice Brand)

Walmart refused to produce any documents showing its internal testing policies, its testing results, or how Walmart treats ingredients and/or products that surpass any internal standards.

Walmart's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

*Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?*¹¹⁶

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Parent's Choice (Walmart)	Little Hearts Strawberry Yogurt Cereal Snack - Stage 3, 9+ months	Snack - other	56.1	--	5.2	26.1	0.941	Charlottesville, VA	Walmart
Parent's Choice (Walmart)	Organic Strawberry Rice Rusks - Stage 2, 6+ months	Snack - teething biscuits & rice rusks/cakes	108	66	26.9	2.4	2.05	Charlottesville, VA	Walmart

¹¹⁵ Hain, PowerPoint Presentation to Food and Drug Administration: *FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹¹⁶ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Walmart (Parent's Choice) Baby Food that Tested High in Toxic Heavy Metals¹¹⁷**B. Campbell (Plum Organics Brand)**

Campbell refused to produce its testing standards and specific testing results to the Subcommittee. Campbell has hidden its policies and the actual level of toxic heavy metals in its products.

Instead of producing any substantive information, Campbell provided a spreadsheet self-declaring that every one of its products “meets criteria.”¹¹⁸ Campbell declined to state what those criteria are.

Campbell's Product Heavy Metal Test Results (Excerpted Entries)¹¹⁹

Product Name	Testing Date	ARSENIC	CADMIUM	LEAD	MERCURY
Plum Organics® Stage 2 Apple & Carrot, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Stage 2 Banana & Pumpkin, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty 4® Blends Strawberry Banana, Greek Yogurt, Kale, Oat & Amaranth, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Snack Bars® Strawberry, 4.02oz (Pack of 6)	10/29/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Nut Butter Bar™ Almond Butter (Pack of 5)	8/29/2018	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria

¹¹⁷ Walmart, *Parent's Choice Organic Strawberry Rice Rusks* (online at www.walmart.com/ip/Parent-s-Choice-Organic-Baby-Rusks-Strawberry-Flavored/171533478) (accessed on Jan. 26, 2021).

¹¹⁸ Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>).

¹¹⁹ *Id.*

Campbell's testing summary hides more than it reveals, since it does not show the levels of heavy metals that the testing found or the levels of heavy metals that would "meet criteria."

The Subcommittee was disturbed that, for mercury, which is a powerful neurotoxin, Campbell notes with asterisks that it has no criterion whatsoever, stating: "No specific threshold established because no high-risk ingredients are used."¹²⁰ However, despite Campbell having no mercury threshold, Campbell still marked every food as "meets criteria" for mercury.¹²¹ This misleading framing—of meeting criteria that do not exist—raises questions about what Campbell's other thresholds actually are, and whether they exist.

Campbell's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

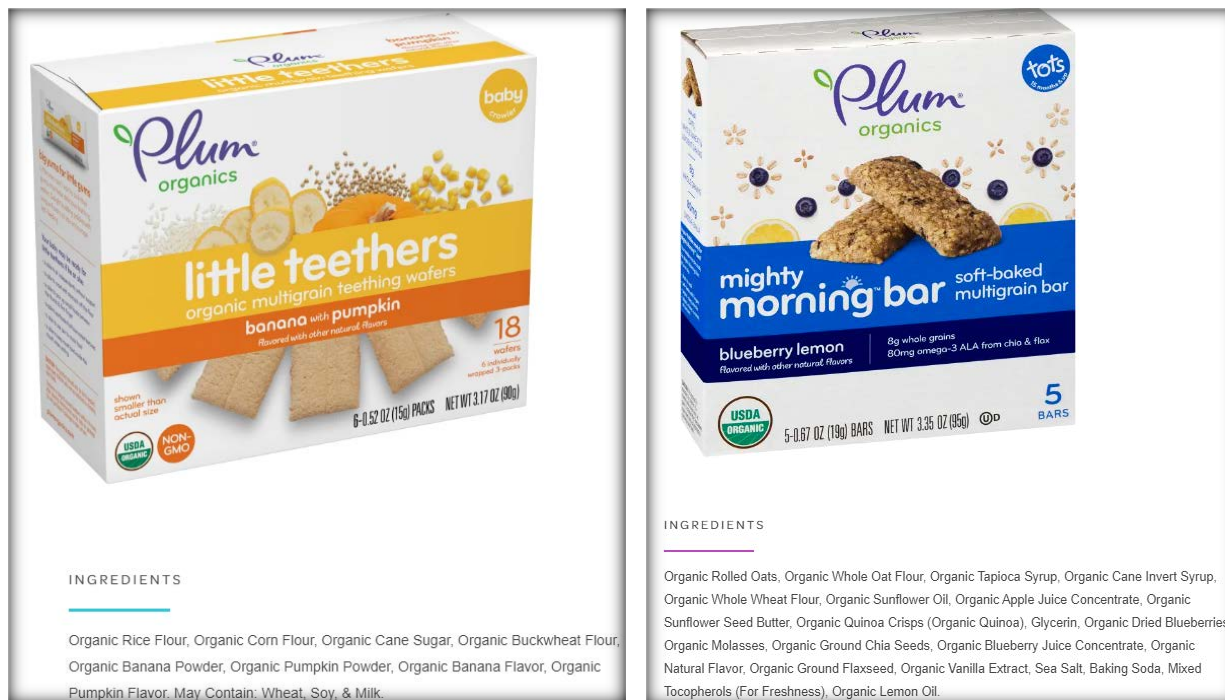
Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?¹²²

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40 *	39	3.4	24.3	<0.137	Cincinnati, OH	Kroger
Plum Organics	Little Teethers Organic Multigrain Teething Wafers - Banana with Pumpkin - Baby Crawler	Snack - teething biscuits & rice rusks/cakes	49.9	--	1.4 *	6.3	0.726	Columbia, SC	Publix

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Plum Organics' Foods That Tested High in Toxic Heavy Metals¹²³**C. Sprout Organic Foods**

Sprout Organic Foods did not respond to the Subcommittee at all. Despite numerous emails to executives and its general information email address, as well as numerous attempts to reach the Sprout central office by telephone, Sprout never responded or made contact with the Subcommittee.

Sprout Organic Foods was acquired by North Castle Partners, a Greenwich, Connecticut private equity firm, in 2015. North Castle Partners also owns such well-known brands as Curves International/Jenny Craig, Palladio Beauty Group, Mineral Fusion, Red Door Spas, Performance Bicycles, Octane Fitness, Ibex Outdoor Clothing, and Doctor's Best.¹²⁴

Whether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products.

¹²³ Plum Organics, *Little Teethers, Banana with Pumpkin* (online at www.plumorganics.com/products/banana-with-pumpkin-wafers/) (accessed Jan. 26, 2021); Plum Organics, *Mighty Morning Bar, Blueberry Lemon* (online at www.plumorganics.com/products/blueberry-lemon-bar/) (accessed Jan. 26, 2021).

¹²⁴ North Castle Partners, *Press Release: North Castle Partners Invests in Sprout Organic Foods, Inc.* (June 29, 2015) (online at www.northcastlepartners.com/wp-content/uploads/2016/01/North-Castle_Sprout-Press-Release.pdf).

Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?¹²⁵

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com

Sprout Organic Food That Tested High in Toxic Heavy Metals¹²⁶

V. FDA HAS FAILED TO CONFRONT THE RISKS OF TOXIC HEAVY METALS IN BABY FOOD. THE TRUMP ADMINISTRATION IGNORED A SECRET INDUSTRY PRESENTATION ABOUT HIGHER AMOUNTS OF TOXIC HEAVY METALS IN FINISHED BABY FOODS.

Despite the well-known risks of harm to babies from toxic heavy metals, FDA has not taken adequate steps to decrease their presence in baby foods. FDA has not issued thresholds for the vast majority of toxic heavy metals in baby foods and does not require warning labels on any baby food products. In the summer of 2019, FDA received a secret presentation from a baby

¹²⁵ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹²⁶ Sprout Organic Foods, *Quinoa Puffs, Apple Kale* (online at www.sproutorganicfoods.com/babies/6-months-and-up/plant-power-puffs/apple-kale-plant-power-puffs) (accessed Jan. 26, 2021).

food manufacturer that revealed that the commercial process of preparing finished baby foods increases their levels of toxic heavy metals. For that manufacturer, Hain (HappyBABY), the process increased inorganic arsenic levels between 28% and 93%. Yet, FDA took no apparent action.

In May 2017, FDA established the Toxic Elements Working Group with the goal of reducing exposure to toxic elements in food, cosmetics, and dietary supplements. FDA claims that the Toxic Elements Working Group is focusing on metals “because high levels of exposure to those metals are likely to have the most significant impact on public health,” and “can be especially harmful to children because of concerns about effects on their neurological development.”¹²⁷ But the working group has not resulted in new or stronger regulations to protect babies from toxic heavy metals in their food.

A. Mercury and Cadmium

FDA has acknowledged the dangers of mercury. Mercury has “no established health benefit” and has been “shown to lead to illness, impairment, and in high doses, death.”¹²⁸ FDA has acknowledged the added risk to babies and children, noting that it is: “paying special attention to children because their smaller body sizes and metabolism may make them more susceptible to the harmful effects of these metals,” including mercury.¹²⁹

Despite these statements, FDA has taken no action to limit mercury in baby food. Instead, FDA has only set mercury standards for wheat, and fish, shellfish, and crustaceans, and they are high—1,000 ppb.¹³⁰ There are no FDA protections for mercury in baby food.

The lack of FDA action on mercury standards stands in contrast to other regulators. The EPA, for example, set a limit of 2 ppb mercury in drinking water, even after taking into account the cost of attainment for industry.¹³¹

¹²⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021); Food and Drug Administration, *What FDA Is Doing to Protect Consumers from Toxic Metals in Foods* (Apr. 20, 2018) (online at www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods).

¹²⁸ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

¹²⁹ *Id.*

¹³⁰ Food and Drug Administration, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (Aug. 2000) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed).

¹³¹ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

Similarly, FDA has taken no action on cadmium in baby food. FDA has issued only one guideline for cadmium, and that is a limit of 5 ppb for bottled water.¹³² The EU has instituted a limit of 10-15 ppb for infant formula.¹³³

B. Lead

FDA acknowledges that there is “no identified safe blood lead level” and that lead is especially dangerous to children:

Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. High levels of lead exposure can seriously harm children’s health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹³⁴

FDA has taken action on bottled water, limiting lead to 5 ppb.¹³⁵ FDA has also taken steps toward regulating lead content in products for older children. FDA has released guidance recommending a maximum lead level of 100 ppb in candy likely to be consumed by children, and 50 ppb in some juices.¹³⁶ It is not sound logic to say that water is unsafe to drink if it contains over 5 ppb lead, but candy and fruit juice can be ten and twenty times higher than that limit.

Unfortunately, it appears that FDA designed these limits to be protective of industry. In its “Supporting Document for Recommended Maximum Level for Lead in Candy,” FDA repeatedly emphasizes achievability by industry, as opposed to safety for children:

- “FDA believes that sugar-based candy products *can be made* with lead levels below” [100 ppb].”
- “We believe *that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb] lead.”
- “We believe that, *if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb].”

¹³² 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

¹³³ European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

¹³⁴ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁵ *Id.*

¹³⁶ *Id.*

- “[E]ven for high-chili-content candy and powdered snack mix products, *we believe that candy with appropriately sourced ingredients will not exceed* [100 ppb] lead.”
- “We believe that *if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed* [100 ppb] lead.”¹³⁷

But FDA has failed to regulate lead levels in baby foods. Manufacturers are free to set their own limits. Hain, for example, used internal soft limits of 100 and 200 ppb lead for the majority of its ingredients.

FDA *has* created what it calls an Interim Reference Level (IRL) for lead, but this standard does not apply to manufacturers and is unhelpful for parents purchasing baby food. An Interim Reference Level is what FDA calls a calculation of “the maximum daily intake for lead from food.”¹³⁸ Above this limit, a person or baby’s blood level would reach a “point of concern.” FDA’s current IRL is 3 µg per day for children. This standard, though perhaps helpful to FDA in researching and evaluating how lead affects our nation’s children, is unworkable for parents. For this standard to be useful to a parent, they would need to know:

- what a µg is (it stands for a microgram);
- how much lead is in each product they are serving their baby;
- how much lead their child is exposed to through tap water; and
- how much lead is in their local environment, such as through lead-based paints.

Obtaining this information is currently impossible for parents because baby food manufacturers do not publicly provide information on the amount of lead in their products. Given the information gaps parents face, it would be most appropriate for FDA to promulgate clear rules for baby food manufacturers that limit the amount of lead in baby food.

C. Arsenic

In the context of arsenic in baby food, there are only two FDA regulations for specific products—an unenforceable draft guidance issued in July 2013, but never finalized, recommending an action level of 10 ppb for inorganic arsenic in single-strength (ready to drink) apple juice, and an August 2020 final guidance, setting an action level for inorganic arsenic in infant rice cereals at 100 ppb.¹³⁹

¹³⁷ Food and Drug Administration, *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children* (Nov. 2006) (online at www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small) (emphasis added).

¹³⁸ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁹ Food and Drug Administration, *Draft Guidance for Industry: Action Level for Arsenic in Apple Juice* (July 2013) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-arsenic-apple-juice); Food and Drug Administration, *Guidance for Industry: Action Level for*

The first problem with these standards is that they cover only a small sliver of the foods babies eat.

The second problem is that they are far too lax to be protective of babies. There is no established safe level of inorganic arsenic consumption for babies. Arsenic exposure has a “significant negative effect on neurodevelopment.”¹⁴⁰ FDA acknowledged that “Low-to-moderate levels of inorganic arsenic appear to be associated with adverse health effects during childhood.”¹⁴¹ Children exposed to water with an arsenic concentration of just 5 ppb “showed significant reductions in Full Scale, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.”¹⁴² This suggests that 5 ppb may be an important threshold, or that the threshold of safety may fall far below that.

Healthy Babies Bright Futures has called for a goal of no measurable amount of inorganic arsenic in baby food.¹⁴³ Consumer Reports suggests that the level of inorganic arsenic should be set as low as 3 ppb for water and fruit juices.¹⁴⁴

FDA has already set inorganic arsenic levels at 10 ppb for bottled water.¹⁴⁵ EPA has similarly set a 10 ppb inorganic arsenic cap on water, as have the European Union and the World Health Organization.¹⁴⁶

Inorganic Arsenic in Rice Cereals for Infants (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

¹⁴⁰ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

¹⁴¹ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

¹⁴² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹⁴³ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹⁴⁴ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

¹⁴⁵ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

¹⁴⁶ Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

FDA is fully aware of the dangers that inorganic arsenic presents to young children, stating that:

There is growing evidence ... that exposure to inorganic arsenic during...infancy...may increase the risk of adverse health effects, including impaired development during...childhood and neurodevelopmental toxicity in infants and young children, and that these adverse effects may persist later in life [C]hildren may likewise be particularly susceptible to neurotoxic effects of inorganic arsenic, e.g., as manifested in intelligence test results in children Also, children three years and younger have the highest exposure to inorganic arsenic because they have 2-3-fold higher intakes of food on a per body mass basis as compared to adults. Therefore, a child's daily exposure to contaminants in food, such as inorganic arsenic in rice, could potentially be much higher than that of adults.¹⁴⁷

Yet, in the one category of baby food for which FDA has finalized a standard—infant rice cereal—it set the maximum inorganic arsenic content at the dangerous level of 100 ppb.

Why did FDA set its level so high? Because in developing the limit, FDA was focused on the level of inorganic arsenic that would cause cancer. FDA disregarded the risk of neurological damage, which happens at a much lower level. In its 2016 Risk Assessment Report, FDA was able to quantify the risk of lung and bladder cancer that inorganic arsenic presents. It was not able to quantify the risks of neurological development for infants.¹⁴⁸ As a result, the 100 ppb limit is too high to adequately protect infants and children from the effects of inorganic arsenic.

The third problem is that FDA's piecemeal approach of setting different inorganic arsenic standards for different products is logically unsound. There can be only one safe level for inorganic arsenic in the foods that babies consume. All finished baby food products should accord with this safe level.

Aside from these guidance documents for infant rice cereal and apple juice, FDA does not regulate toxic heavy metals in other baby food products.

One example of how this approach is failing is with FDA's decision to release draft guidance for apple juice, but not any other fruits juices. Based on the testing results the Subcommittee reviewed, baby food companies routinely exceed this draft limit of 10 ppb in other types of commonly consumed juices. Gerber, for example, used grape juice concentrate registering at 39 ppb inorganic arsenic. But because it was grape juice, as opposed to apple

¹⁴⁷ Food and Drug Administration, *Supporting Document For Action Level For Inorganic Arsenic In Rice Cereals For Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁴⁸ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

juice—which, from a safety perspective, is a distinction without a difference—Gerber incorporated in its products juice concentrate with high arsenic levels.

The fourth problem with FDA’s piecemeal approach is that it appears designed to be protective of baby food manufacturers. In developing the infant rice cereal limit of 100 ppb, FDA considered an “achievability assessment.” The achievability assessment considered “manufacturers’ ability to achieve hypothetical maximum limits for inorganic arsenic in infant rice cereals....”¹⁴⁹ FDA considered samples taken from three time periods: 2011-2013, 2014, and 2018. As shown below, over time, the number of samples that tested under 100 ppb inorganic arsenic increased from 36% to 76% of the total number of samples. FDA noted that this increase meant “alternate sources of rice are available to enable infant rice cereal manufacturers to supply the market and meet the” 100 ppb level.¹⁵⁰ In short, FDA’s standard reflects manufacturers’ ease of compliance, rather than babies’ safety.

If it is not possible, or it is exceedingly costly, to source ingredients like rice that achieve a safe level, then baby food manufacturers should find substitutes for those ingredients. Our nation’s children should not bear lifelong health burdens because of a manufacturer’s preference for tainted ingredients.

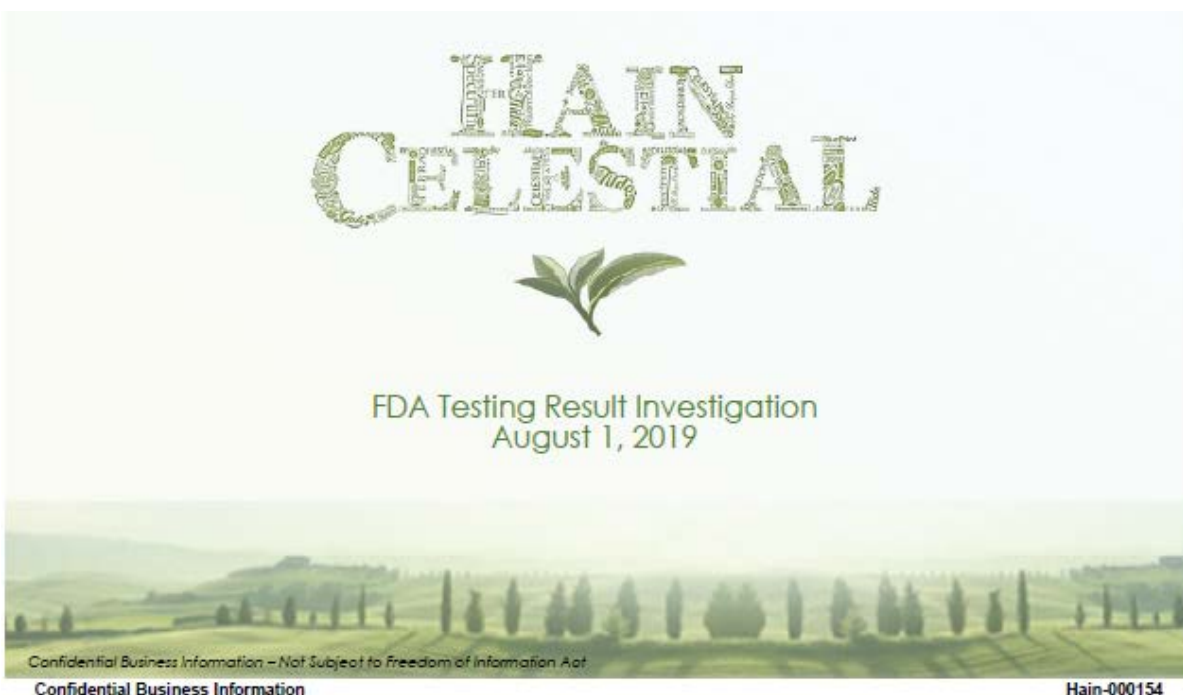
D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.

On August 1, 2019, the Trump administration received a secret industry presentation that disclosed higher risks of toxic heavy metals in finished baby food products. Hain (Earth’s Best Organic) revealed the finding in a presentation to FDA entitled “FDA Testing Result Investigation.”¹⁵¹

¹⁴⁹ Food and Drug Administration, *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁵⁰ *Id.*

¹⁵¹ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).



Hain revealed that half (10 of 21) of the finished rice products that Hain tested contained 100 ppb or more of inorganic arsenic—exceeding FDA’s standard for infant rice cereal. One product contained almost 30% more, registering at 129 ppb inorganic arsenic.

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

Hain’s average level of inorganic arsenic in its finished rice foods was 97.62 ppb, which nearly matches FDA’s dangerously high 100 ppb level for inorganic arsenic for infant rice cereal.

Hain claims that it “revised its internal policies and testing standards to conform to FDA’s non-binding recommendations.”¹⁵² In 2016, FDA instituted draft guidance (which is now final) for inorganic arsenic in infant rice cereal at the dangerously high level of 100 ppb. However, Hain has not consistently abided by those limits.

FDA also learned that Hain’s policy to test ingredients underrepresented the levels of toxic heavy metals in its finished baby foods. Hain’s finished products contained between 28% and 93% more inorganic arsenic than Hain estimated they would based on Hain’s ingredient

¹⁵² Letter from Kelly B. Kramer, Counsel for The Hain Celestial Group, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9_Redacted.pdf).

testing method.¹⁵³ Hain found higher levels of arsenic in *all* finished foods tested for this FDA presentation than were reflected in tests of individual raw ingredients. This revelation means that every single finished good containing brown rice had more arsenic than the company's estimates, which were based on testing the raw ingredients.

After seeing these results, FDA was put on notice that finished baby foods pose an even higher risk to babies than reflected in company tests of the raw ingredients that go into those finished products.

Final Product Data Compared to Raw Ingredient Data, From Hain's Presentation to FDA¹⁵⁴

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1017814	3/2/19	BN A 0636	94	80.3	43%	9/8/17	199987	B160004661	Total Arsenic	54	56.3
1038929		BN C 1139	83					B160004870	Total Arsenic	58	
1039633		BN F 1648	64				B160004759	Total Arsenic	57		
							B160004659	Total Arsenic	54		
						197594	B160004870	Total Arsenic	58		
								B160004759	Total Arsenic	57	
1039750	3/8/19	BN E	74	74.0	29%	9/14/17	200408	B160004871	Total Arsenic	60	57.3
								B160004870	Total Arsenic	58	
								B160004661	Total Arsenic	54	
1041752	3/20/19	BN G	92	96.0	57%	9/26/17	200651	B160005149	Total Arsenic	65	61.3
1037933		BN E 1536	67								
1041751	3/21/19	BN B 0832	108			9/27/17		B160004873	Total Arsenic	58	
1038677		BN B 0932	116					B160005157	Total Arsenic	62	
1026932		BN D 1248	97					B160004871	Total Arsenic	60	
								B160005148	Total Arsenic	61	
1044380	4/11/19	BH C	100	100.0	69%	10/18/17	201873	B160004872	Total Arsenic	55	59.0
								B160005152	Total Arsenic	61	
								B160005305	Total Arsenic	69	
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005306	Total Arsenic	76	67.0
								B160005512	Total Arsenic	62	
									B160005152	Total Arsenic	
1024210	6/6/19	BN I 2241	94	101.0	61%	12/13/17	206697	B160005515	Total Arsenic	63	62.7
547103		BN I 2339	115								
1013927	6/7/19	BN E 1540	92			12/14/17		B160005513	Total Arsenic	60	
1026516		BN H 2123	104								
1074288	6/8/19	BNE 1406	105			12/15/17		B160005150	Total Arsenic	65	
1035738	6/13/19	BN J 0000	96			12/20/17					
1047511	6/27/19	BN C 1142	100	100.0	56%	1/3/18	208226	B160006190	Inorganic Arsenic	73	64.0
								B160005581	Total Arsenic	55	
1063061	7/19/19	BN J	115	115.0	43%	1/25/18	208594	B160006189	Inorganic Arsenic	81	80.5
								B160006191	Inorganic Arsenic	80	
								B160006265	Inorganic Arsenic	77	
1027437	8/18/19	BN A 0703	97	97.0	28%	2/24/18	210374	B160006263	Inorganic Arsenic	74	75.7
								B160006260	Inorganic Arsenic	76	
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	B160007235	Inorganic Arsenic	66	82.5
								B160006755	Inorganic Arsenic	99	

Hain admitted to FDA in its presentation that "Brown Rice Flour testing results do not appear to be correlated to finished good results data."¹⁵⁵ They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

¹⁵³ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

What can account for this increase in inorganic arsenic from the time the ingredients are tested to the time the products are finished? Hain conveyed to FDA that the cause of the increase was Hain's use of a dangerous additive, stating: "Preliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor." Although this additive may only make up roughly 2% of the final good, Hain suggested it was still responsible for the spike in the levels of inorganic arsenic in the finished baby food.¹⁵⁶

Hain's finding accords with the Subcommittee's own. In the test results we reviewed, Hain used vitamin pre-mix that contained 223 ppb arsenic.¹⁵⁷ This ingredient also contained 352 ppb lead, a matter not even addressed in the FDA presentation.

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)¹⁵⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Therefore, naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

FDA did not appear to take any unplanned actions on behalf of babies' safety after it received Hain's presentation. FDA did finalize a previously planned guidance, setting a limit of 100 ppb inorganic arsenic in infant rice cereal. But it did not initiate regulation of additives like Hain's vitamin/mineral pre-mix. Moreover, it has not mandated that baby food manufacturers test finished goods.

E. Corporate Testing Policies Hide the Truth: In Addition to Hain, Beech-Nut and Gerber Also Fail to Test Finished Product, Risking an Undercount of Toxic Heavy Metals in Their Finished Baby Foods.

Hain (Earth's Best Organic) revealed to FDA that its policy to test only its ingredients, and not its final product, is underrepresenting the levels of toxic heavy metals in its baby foods. Unfortunately, Hain is not alone. The majority of baby food manufacturers, including Beech-Nut and Gerber, employ the same policy of testing only ingredients.¹⁵⁹ That policy recklessly

¹⁵⁶ *Id.*

¹⁵⁷ Hain, Raw Material Pre-Shipment Test Data History (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

¹⁵⁸ *Id.*

¹⁵⁹ Letter from the President and CEO of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf) ("we do not test finished goods"); Letter from the Chief Executive Officer of Gerber Products Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 19,

endangers babies and children and prevents the companies from even knowing the full extent of the danger presented by their products.

As the Hain presentation lays bare, ingredient testing does not work. Hain's finished baby foods had more arsenic than their ingredients 100% of the time—28-93% more inorganic arsenic.¹⁶⁰ That means that only testing ingredients gives the false appearance of lower-than-actual toxic heavy metal levels.

VI. RECOMMENDATIONS AND CONSIDERATIONS FOR INDUSTRY, PARENTS, AND REGULATORS: DO HIGHLY TAINTED INGREDIENTS LIKE RICE BELONG IN BABY FOOD?

Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell unsafe products. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and federal regulators have broken the faith.

Step one to restoring that trust is for manufacturers to voluntarily and immediately reduce the levels of toxic heavy metals in their baby foods to as close to zero as possible. If that is impossible for foods containing certain ingredients, then those ingredients should not be included in baby foods.

One example of an ingredient that might not be suitable for baby foods is rice. Throughout this report, rice appeared at or near the top of every list of dangerous baby foods.

- For Hain (Earth's Best Organic), organic brown rice was the ingredient that tested highest in inorganic arsenic—309 ppb. Indeed, the majority of Hain ingredients that exceeded 100 ppb inorganic arsenic in testing (13 of 24) were organic brown rice flour.¹⁶¹
- For Beech-Nut, the majority of its ingredients that tested over 100 ppb inorganic arsenic (27 of 45) were rice-based (either rice, rice flour, or organic rice).¹⁶²

2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7_Redacted.pdf) (Gerber's policy is to "regularly test our ingredients, and periodically test... finished goods"); Hain, *Testing And Release Procedure For Baby Food Ingredients* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/8_Redacted.pdf) (Hain only tests raw ingredients; their testing policy applies only to ingredients and the vast majority of the testing information they provided to the Subcommittee was raw ingredient testing.).

¹⁶⁰ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁶¹ *Id.*

¹⁶² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

- A significant number of the Nurture products that exceeded 100 ppb inorganic arsenic were rice products.¹⁶³
- Gerber used 67 batches of rice flour with over 90 ppb inorganic arsenic.¹⁶⁴

Further, rice and rice flour constitute a large proportion by volume of the baby foods that contain them. Therefore, increased toxic heavy metal levels in rice and rice flour could have a significant impact on the safety of the finished product.

If certain ingredients, like rice, are highly tainted, the answer is not to simply lower toxic heavy metal levels as much as possible for those ingredients, the answer is to stop including them in baby foods. The Subcommittee urges manufacturers to make this change voluntarily.

Similar considerations must be made for other ingredients that consistently contain higher levels of toxic heavy metals—ingredients like cinnamon, amylase, BAN 800, and vitamin premix. Manufacturers suggest that these additives, though high in toxic heavy metals, are not a concern because they make up a low percentage of the final food product. However, those manufacturers do not test their final food products, which is the only way to determine safety. Manufacturers should voluntarily commit to testing all of their finished baby food products, as opposed to just the ingredients. If they refuse, FDA should require them to do so.

The Subcommittee recommends the following:

- **Mandatory Testing:** Only one of the companies reviewed by the Subcommittee routinely tests its finished baby foods, even though the industry is aware that toxic heavy metals levels are higher after food processing. Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.
- **Labeling:** Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels.
- **Voluntary Phase-Out of Toxic Ingredients:** Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.
- **FDA Standards:** FDA should set maximum levels of inorganic arsenic, lead, cadmium, and mercury permitted in baby foods. One level for each metal should apply across all baby foods. The level should be set to protect babies against the neurological effects of toxic heavy metals.
- **Parental Vigilance:** Parents should avoid baby food products that contain ingredients testing high in heavy metals, such as rice products. The implementation of recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

¹⁶³ Nurture, *Heavy Metal Test Results For Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

¹⁶⁴ Gerber, *Raw Material Heavy Metal Testing* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

VII. CONCLUSION

The Subcommittee's investigation proves that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.

Last year, the Trump administration ignored new information contained in a secret industry presentation to federal regulators about toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain, the maker of Earth's Best Organic baby food, which revealed that finished baby food products contain even higher levels of toxic heavy metals than estimates based on individual ingredient test results. One heavy metal in particular, inorganic arsenic, was repeatedly found to be present at 28-93% higher levels than estimated.

The time is now for FDA to determine whether there is any safe exposure level for babies to inorganic arsenic, lead, cadmium, and mercury, to require manufacturers to meet those levels, and to inform consumers through labels.

**BRAZORIA COUNTY DISTRICT CLERK
RHONDA BARCHAK**

Process Request

Please Print All Information Clearly & Neatly

Cause No. 111847-CV For each party served you must furnish 1 copy of the document(s).

DOCUMENT(S) TO BE SERVED Citation with Original Petition

Name/Business to be Served:

1. Name The Hain Celestial Group, Inc.
Registered Agent (if applicable) CT Corporation System
Address 1999 Bryan St., Ste. 900
City, State, Zip Dallas, Texas 75201
2. Name Whole Foods Market Inc.
Registered Agent (if applicable) CT Corporation System
Address 1999 Bryan St., Ste. 900
City, State, Zip Dallas, Texas 75201

Service By (check one)

- ☐ Sheriff
- ☐ Certified Mail **Check One:** ☐ Restricted Delivery ☐ Non-Restricted Delivery
- ☐ Pickup by whom: _____
- ☐ Return by mail to: _____
- ☒ Return by e-mail to (Provide e-mail address): e-service@arnolditkin.com
- ☐ Citation by Publication (Please fill out the box below)
- ☐ Citation by Posting at Courthouse Door (Please fill out the box below)

<input type="checkbox"/> Divorce/Family Citation with or without Children Name and Address of Publication: _____ Relief Request Required: _____ Date of Birth/Place of Birth for Each Child Required: _____ <input type="checkbox"/> Civil **As per TRCP 115, attach legal description of property if applicable and state relief requested Name and Address of Publication: _____ Relief Request Required: _____ Property Description: _____

Notes: _____

Service Requested by:

Name Kurt Arnold /s/ Kurt Arnold
Printed name Signature

Phone No. 713-222-3800 Email kbateam@arnolditkin.com

CIVIL DOCKET - CAUSE NO. 111847-CV

149th District Court

NAMES OF PARTIES	ATTORNEYS	KIND OF ACTION	DATE OF FILING
Sarah Palmquist, et al vs. The Hain Celestial Group, Inc., et al	KURT B. ARNOLD -Pla Atty	Injury or Damage - Other	03/10/2021
			Jury Fee Paid: \$
	-Def Atty		Paid by: Date:

[illegible]

**CAUSE NO. 111847-CV
149th District Court**

THE STATE OF TEXAS

CITATION

**TO: The Hain Celestial Group, Inc.
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201**

Defendant

NOTICE:

You have been sued. You may employ an attorney. If you or your attorney does not file a written answer with the Clerk who issued this Citation by 10:00 a.m. on the Monday next following the expiration of 20 days after you were served this **Citation** and **Original Petition** a Default Judgment may be taken against you. In addition to filing a written answer with the clerk, you may be required to make initial disclosures to the other parties of this suit. These disclosures generally must be made no later than 30 days after you file your answer with the clerk. Find out more at TexasLawHelp.org. If filing Pro se, said answer may be filed by mailing same to: Brazoria County District Clerk's office, 111 E. Locust, Suite 500, Angleton, TX 77515-4678 or by bringing said answer in person to the aforementioned address.

The case is presently pending before the **149th District Court** of Brazoria County sitting in Angleton, Texas, and was filed on the **10th day of March, 2021**. It bears Cause No. **111847-CV** and Styled:

**Sarah Palmquist, et al
vs.
The Hain Celestial Group, Inc., et al**

The name and address of the Attorney filing this action (or Party, if Pro Se) is **Kurt B. Arnold, Arnold & Itkin, LLP, 6009 Memorial Drive, Houston, TX 77007**.

The nature of the demands of said Plaintiff is shown by a true and correct copy of Plaintiff's Petition accompanying this Citation.

Issued under my hand and the seal of said Court, at Angleton, Texas, on the **10th day of March, 2021**.

**RHONDA BARCHAK, DISTRICT CLERK
Brazoria County, Texas**

By _____, Deputy
Jody Stutts



File Copy

RETURN OF SERVICE

CAUSE NO. 111847-CV 149th District Court

SARAH PALMQUIST, ET AL
VS.
THE HAIN CELESTIAL GROUP, INC., ET AL

The Hain Celestial Group, Inc.
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Came to hand on the _____ day of _____, 20__ at _____, o'clock _____.m., and executed in _____ County, Texas by delivering to each of the within named parties in person, a true copy of this CITATION with the date of delivery endorsed thereon, together with the accompanying copy of the Original Petition at the following times and places, to-wit:

NAME	DATE	TIME	PLACE, COURSE, AND DISTANCE FROM COURTHOUSE	MILEAGE

and not executed as to (NAME) _____

and the cause or failure to execute this process is for the following reason: _____

The diligence used in finding said (NAME) being: _____

FEES:

Serving Citation and Copy	\$ _____	_____, Officer
Mileage: _____ miles @ \$ _____ per mile	\$ _____	_____ County, Texas
Total	\$ _____	_____ Deputy/Authorized Person

COMPLETE IF YOU ARE A PERSON OTHER THAN A SHERIFF, CONSTABLE, OR CLERK OF THE COURT.

In accordance with Rule 107: The officer or authorized person who serves, or attempts to serve, a citation shall sign the return. The return must either be verified or be signed under penalty of perjury. A return signed under penalty of perjury must contain the statement below in substantially the following form:

"My name is _____, my date of birth is _____, and my
(First, Middle, Last)
address is _____
(Street, City, State, Zip Code, Country)

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed in _____ County, State of _____, on the ____ day of _____, 20__.

Declarant/Authorized Process Server

(Id No. and expiration of certification)

**CAUSE NO. 111847-CV
149th District Court**

THE STATE OF TEXAS

CITATION

TO: **Whole Foods Market, Inc.**
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Defendant

NOTICE:

You have been sued. You may employ an attorney. If you or your attorney does not file a written answer with the Clerk who issued this Citation by 10:00 a.m. on the Monday next following the expiration of 20 days after you were served this **Citation** and **Original Petition** a Default Judgment may be taken against you. In addition to filing a written answer with the clerk, you may be required to make initial disclosures to the other parties of this suit. These disclosures generally must be made no later than 30 days after you file your answer with the clerk. Find out more at TexasLawHelp.org. If filing Pro se, said answer may be filed by mailing same to: Brazoria County District Clerk's office, 111 E. Locust, Suite 500, Angleton, TX 77515-4678 or by bringing said answer in person to the aforementioned address.

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Sarah Palmquist, et al
vs.
The Hain Celestial Group, Inc., et al

The name and address of the Attorney filing this action (or Party, if Pro Se) is **Kurt B. Arnold, Arnold & Itkin, LLP, 6009 Memorial Drive, Houston, TX 77007**.

The nature of the demands of said Plaintiff is shown by a true and correct copy of Plaintiff's Petition accompanying this Citation.

Issued under my hand and the seal of said Court, at Angleton, Texas, on the **10th day of March, 2021**.

RHONDA BARCHAK, DISTRICT CLERK
Brazoria County, Texas

By _____, Deputy
Jody Stutts



File Copy

RETURN OF SERVICE

CAUSE NO. 111847-CV 149th District Court

SARAH PALMQUIST, ET AL
VS.
THE HAIN CELESTIAL GROUP, INC., ET AL

Whole Foods Market, Inc.
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Came to hand on the _____ day of _____, 20__ at _____, o'clock _____.m., and executed in _____ County, Texas by delivering to each of the within named parties in person, a true copy of this CITATION with the date of delivery endorsed thereon, together with the accompanying copy of the Original Petition at the following times and places, to-wit:

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and not executed as to (NAME) _____

and the cause or failure to execute this process is for the following reason: _____

The diligence used in finding said (NAME) being: _____

FEES:

Serving Citation and Copy	\$ _____	_____, Officer
Mileage: _____ miles @ \$ _____ per mile	\$ _____	_____ County, Texas
Total	\$ _____	_____ Deputy/Authorized Person

COMPLETE IF YOU ARE A PERSON OTHER THAN A SHERIFF, CONSTABLE, OR CLERK OF THE COURT.

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(Street, City, State, Zip Code, Country)

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed in _____ County, State of _____, on the ____ day of _____, 20__.

Declarant/Authorized Process Server

(Id No. and expiration of certification)

**CAUSE NO. 111847-CV
149th District Court**

THE STATE OF TEXAS

CITATION

TO: **Whole Foods Market, Inc.**
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Defendant

NOTICE:

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Sarah Palmquist, et al
vs.
The Hain Celestial Group, Inc., et al

The name and address of the Attorney filing this action (or Party, if Pro Se) is **Kurt B. Arnold, Arnold & Itkin, LLP, 6009 Memorial Drive, Houston, TX 77007**.

The nature of the demands of said Plaintiff is shown by a true and correct copy of Plaintiff's Petition accompanying this Citation.

Issued under my hand and the seal of said Court, at Angleton, Texas, on the **10th day of March, 2021**.

RHONDA BARCHAK, DISTRICT CLERK
Brazoria County, Texas

By _____, Deputy
Jody Stutts



POOR ORIGINAL

Original

RETURN OF SERVICE

CAUSE NO. 111847-CV 149th District Court

SARAH PALMQUIST, ET AL
VS.
THE HAIN CELESTIAL GROUP, INC., ET AL

Whole Foods Market, Inc.
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Came to hand on the _____ day of _____, 20__ at _____, o'clock _____.m., and executed in _____ County, Texas by delivering to each of the within named parties in person, a true copy of this CITATION with the date of delivery endorsed thereon, together with the accompanying copy of the Original Petition at the following times and places, to-wit:

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SERVICE AFFIDAVIT ATTACHED				

and not executed as to (NAME) _____

and the cause or failure to execute this process is for the following reason: _____

The diligence used in finding said (NAME) being: _____

FEES:

Serving Citation and Copy	\$ _____	_____, Officer
Mileage: _____ miles @ \$ _____ per mile	\$ _____	_____ County, Texas
Total	\$ _____	_____ Deputy/Authorized Person

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address is _____
(Street, City, State, Zip Code, Country)

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed in _____ County, State of _____, on the ____ day of _____, 20__.

Declarant/Authorized Process Server

(Id No. and expiration of certification)

AFFIDAVIT OF SERVICE

State of Texas

County of Brazoria

149th District Court

Case Number: 111847-CV

Plaintiff:

**Sarah Palmquist, Individually
and as Next Friend of
E.P., a Minor,
and Grant Palmquist**

vs.

Defendant:

**The Hain Celestial Group, Inc.; and
Whole Foods Market, Inc.**

For:

Kurt Arnold
Arnold & Itkin, LLP
6009 Memorial Drive
Houston, TX 77007

Received by Lexitas on the 12th day of March, 2021 at 2:30 pm to be served on **Whole Foods Market, Inc. b/s r/a CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201.**

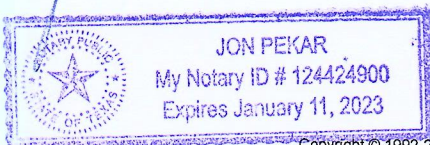
I, Charles P Goodson, being duly sworn, depose and say that on the **12th day of March, 2021 at 2:45 pm, I:**

Executed service by hand delivering a true copy of the **Citation, Copy of Plaintiff's Original Petition** to: **Latoya Sterns**, an authorized acceptance agent employed by **Registered Agent CT Corporation System, Inc.**, who is authorized to accept service of process for **Whole Foods Market, Inc.**, at the address of: **1999 Bryan Street, Suite 900, Dallas, TX 75201**, and informed said person of the contents therein, in compliance with state statutes.

"I certify that I am over the age of 18, have no interest in the above action, and am a Certified Process Server in good standing in the judicial circuit in which the process was served. I have personal knowledge of the facts set forth in this affidavit, and they are true and correct."

Subscribed and Sworn to before me on the 12th day of March, 2021 by the affiant who is personally known to me.

NOTARY PUBLIC





Charles P Goodson
PSC-6487 Expires 2/28/2023

Lexitas
4299 San Felipe
Suite 350
Houston, TX 77027
(713) 375-0121

Our Job Serial Number: ONT-2021001251
Ref: 348247



**CAUSE NO. 111847-CV
149th District Court**

THE STATE OF TEXAS

CITATION

TO: **The Hain Celestial Group, Inc.**
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Defendant

NOTICE:

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Sarah Palmquist, et al
vs.
The Hain Celestial Group, Inc., et al

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The nature of the demands of said Plaintiff is shown by a true and correct copy of Plaintiff's Petition accompanying this Citation.

Issued under my hand and the seal of said Court, at Angleton, Texas, on the **10th day of March, 2021**.

RHONDA BARCHAK, DISTRICT CLERK
Brazoria County, Texas

By _____, Deputy
Jody Stutts

**Service Copy**

RETURN OF SERVICE

CAUSE NO. 111847-CV 149th District Court

SARAH PALMQUIST, ET AL
VS.
THE HAIN CELESTIAL GROUP, INC., ET AL

The Hain Celestial Group, Inc.
By serving its Registered Agent
CT Corporation System
1999 Bryan St., Ste. 900
Dallas, Texas 75201

Came to hand on the _____ day of _____, 20__ at _____, o'clock _____.m., and executed in _____ County, Texas by delivering to each of the within named parties in person, a true copy of this CITATION with the date of delivery endorsed thereon, together with the accompanying copy of the Original Petition at the following times and places, to-wit:

NAME	DATE	TIME	PLACE, COURSE, AND DISTANCE FROM COURTHOUSE	MILEAGE
SERVICE AFFIDAVIT ATTACHED				

and not executed as to (NAME) _____

and the cause or failure to execute this process is for the following reason: _____

The diligence used in finding said (NAME) being: _____

FEES:

Serving Citation and Copy	\$ _____	_____, Officer
Mileage: _____ miles @ \$ _____ per mile	\$ _____	_____ County, Texas
Total	\$ _____	_____ Deputy/Authorized Person

COMPLETE IF YOU ARE A PERSON OTHER THAN A SHERIFF, CONSTABLE, OR CLERK OF THE COURT.

In accordance with Rule 107: The officer or authorized person who serves, or attempts to serve, a citation shall sign the return. The return must either be verified or be signed under penalty of perjury. A return signed under penalty of perjury must contain the statement below in substantially the following form:

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address is _____
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I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed in _____ County, State of _____, on the ____ day of _____, 20__.

Declarant/Authorized Process Server

(Id No. and expiration of certification)

AFFIDAVIT OF SERVICE

State of Texas

County of Brazoria

149th District Court

Case Number: 111847-CV

Plaintiff:

**Sarah Palmquist, Individually
and as Next Friend of
E.P., a Minor,
and Grant Palmquist**

vs.

Defendant:

**The Hain Celestial Group, Inc.; and
Whole Foods Market, Inc.**

For:

Kurt Arnold
Arnold & Itkin, LLP
6009 Memorial Drive
Houston, TX 77007

Received by Lexitas on the 15th day of March, 2021 at 2:30 pm to be served on **The Hain Celestial Group, Inc. b/s
r/a CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201.**

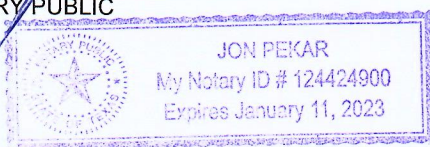
I, Charles P Goodson, being duly sworn, depose and say that on the **16th day of March, 2021 at 2:54 pm, I:**

Executed service by hand delivering a true copy of the **Citation, Copy of Plaintiff's Original Petition** to: **Latoya Sterns**, an authorized acceptance agent employed by **Registered Agent CT Corporation System, Inc.**, who is authorized to accept service of process for **The Hain Celestial Group, Inc.**, at the address of: **1999 Bryan Street, Suite 900, Dallas, TX 75201**, and informed said person of the contents therein, in compliance with state statutes.

"I certify that I am over the age of 18, have no interest in the above action, and am a Certified Process Server in good standing in the judicial circuit in which the process was served. I have personal knowledge of the facts set forth in this affidavit, and they are true and correct."

Subscribed and Sworn to before me on the 16th day of
March, 2021 by the affiant who is personally known to
me.

NOTARY PUBLIC




Charles P Goodson
PSC-6487 Expires 2/28/2023

Lexitas
4299 San Felipe
Suite 350
Houston, TX 77027
(713) 375-0121

Our Job Serial Number: ONT-2021001276
Ref: 348247



CAUSE NO. 111847-CV

Sarah Palmquist, Individually	§	IN THE DISTRICT COURT OF
and as Next Friend of	§	
E.P., a Minor,	§	
and Grant Palmquist,	§	
	§	
<i>Plaintiffs,</i>	§	
	§	
v.	§	BRAZORIA COUNTY, TEXAS
	§	
The Hain Celestial Group, Inc.; and	§	
Whole Foods Market, Inc.	§	
	§	
<i>Defendants.</i>	§	149 th JUDICIAL DISTRICT

FIRST AMENDED PETITION

COME NOW, Plaintiffs, Sarah Palmquist, Individually and as Next Friend of E.P., a Minor, and Grant Palmquist (collectively “Plaintiffs”) complaining of The Hain Celestial Group, Inc. and Whole Foods Market Rocky Mountain/Southwest, L.P. (collectively referred to as “Defendants”), and would respectfully show the Court the following:

I.

NATURE OF ACTION

1. A recent Congressional committee report concluded that several commercial baby foods are tainted with significant levels of toxic heavy metals including arsenic, lead, cadmium, and mercury.¹ Both the Food and Drug Administration and the World Health Organization agree that these metals are not only dangerous to human health in general but are particularly dangerous to infants and young children, who are highly vulnerable to their

¹ See Exhibit 1: “Baby Foods Are Tainted with Dangerous Levels of Arsenic, Cadmium, and Mercury,” Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, February 4, 2021.

neurotoxic effects. Specifically, studies have shown that infants and children exposed to high levels of these toxic metals have a high risk of developing serious neurological and developmental disorders. In short, “[t]oxic heavy metals endanger infant neurological development and long-term brain function.”²

2. The Hain Celestial Group, Inc. (“Hain”) sells organic baby food nationwide under the “Earth’s Best Organic” brand name. As the Report points out, Hain knew that its baby food contained high levels of toxic metals yet chose to continue to sell its products to children while hiding the true nature of their contents.

3. Plaintiffs Grant and Sarah Palmquist were innocent consumers who purchased the Earth’s Best Organic products convinced that they were buying the highest quality and safest nutrition available for their infant child E.P. Sadly, Hain’s products have severely and permanently damaged E.P.’s brain and neurological function. Plaintiffs bring this suit for damages they have suffered due to Defendants’ production, marketing, distribution, and sale of baby food that contained unsafe levels of toxic heavy metals that have permanently injured E.P.

II.

JURISDICTION

4. Plaintiffs’ claims against all defendants are intended to and do arise exclusively under the laws of Texas.

5. The Court has jurisdiction over this case because Plaintiffs seek damages within its jurisdictional limits. Further, this case is not removable because Plaintiffs have not made any federal claims and complete diversity is lacking. 28 U.S.C. § 1332(c)(1). Plaintiffs

² *Id.* at 2.

and Defendant Whole Foods Market Rocky Mountain/Southwest, L.P. are residents of the state of Texas. In addition, to the absence of federal question or diversity jurisdiction, removal jurisdiction does not exist as Whole Foods Market Rocky Mountain/Southwest, L.P. is a corporate citizen of Texas. *See* 28 U.S.C. § 1441(b)(2) (“A civil action otherwise removable solely on the basis of jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.”).

III.

VENUE

6. Venue is proper in this County pursuant to Texas Civil Practice and Remedies Code Section 15.002(a)(1) because all or a substantial part of the events or omissions giving rise to the claim occurred in this County. Specifically, Plaintiffs are residents of Brazoria County. Further, Brazoria County is the place where E.P. consumed the majority of Earth’s Best Organic products that caused his injuries, thus Plaintiffs’ cause of action accrued here. *See* TEX. CIV. PRAC. & REM. CODE 15.002(a)(4).

IV.

DISCOVERY

7. Plaintiffs request that discovery in this matter be conducted under Level 2 of the Texas Rules of Civil Procedure.

V.

PARTIES

8. Plaintiff Sarah Palmquist resides in Texas and is E.P.’s natural mother. Sarah Palmquist brings claims individually and on behalf of and as next friend of her minor child

E.P.

9. Plaintiff Grant Palmquist resides in Texas and is E.P.’s natural father.

10. The Hain Celestial Group, Inc., is a Delaware corporation with its principal place of business in New York. Hain sells its baby food under the “Earth’s Best Organic” brand name. Earth’s Best Brand baby food is sold nationwide, including throughout the state of Texas. Hain Celestial Group, Inc. can be served with process through its registered agent: CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

11. Defendant Whole Foods Market Rocky Mountain/Southwest, L.P. is a Texas limited partnership with its principal place of business in Austin, Texas. Whole Foods Market Rocky Mountain/Southwest, L.P. owns and operates the Whole Foods stores in Texas. Whole Foods Market Rocky Mountain/Southwest, L.P. can be served via its registered agent: CT Corporation System, at 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

VI.

FACTS

The February 4, 2021 Committee Report

12. In August 2019, the FDA received a secret slide presentation from Hain, the maker of Earth’s Best Organic baby food, that revealed the presence of high levels of toxic heavy metals in Hain’s finished baby food products. The presentation, entitled “FDA Testing Results Investigation” revealed that half of Hain’s finished rice products tested contained 100 ppb (parts per billion) or more of organic arsenic with one product registering as high as 129 ppb. This represents a level that matches or exceeds the FDA’s “dangerously high” 100 ppb level for inorganic arsenic for infant rice cereal.

13. The FDA learned that Hain's policy to test ingredients severely underrepresented the levels of heavy toxic metals in Hain's finished baby food products. In fact, Hain's finished baby food products contained between 28% and 93% more inorganic arsenic than Hain estimated it would find based on Hain's ingredient testing method. Hain tested several products for the FDA presentation and found that all of its finished baby food products contained higher levels of arsenic than were reflected in tests of Hain's individual raw ingredients. These tests put the FDA on notice that Hain's finished baby foods posed a high risk to babies that consumed Hain products.

14. Armed with this knowledge, the United States House of Representatives Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy investigated Hain and several other organic baby food providers and subsequently released a report entitled "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury." The Report gathered findings regarding the presence of heavy toxic metals in organic baby food products like Hain's Earth's Best Organic line. Hain provided the Subcommittee with its internal testing policies, test results for both its ingredients and finished products, and documentation regarding Hain's policies as to its ingredients and finished products that exceeded its internal testing limits. The Report outlines several disturbing findings regarding the level of dangerous heavy metals in Hain's organic baby food products.

Hain products contain high levels of toxic metals.

15. Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals that are extremely dangerous to human health and particularly dangerous to babies and children especially when consumed in high levels. Babies and children are most vulnerable to the

damaging neurotoxic effects these metals can have on the neurological system where even low levels of exposure can cause irreversible brain damage.

16. According to the Report, Hain distributed and sold its organic baby food products despite these products containing dangerously high amounts of arsenic, lead, cadmium, and mercury. Hain's internal company standards permitted sale of its products despite these dangerously high levels of these toxic metals. Hain's internal policies set a standard of 200 ppb for arsenic, lead, and cadmium (the Report found that Hain did not test for mercury) in some of its ingredients. Sadly, Hain far exceeded its internal standards and used ingredients containing 353 ppb lead and 309 ppb arsenic. To compound matters, Hain likely added additional ingredients, like its vitamin/mineral pre-mix, that also contained high levels toxic heavy metals.

Heavy toxic metals like those in Hain's baby food products are a danger to young children.

17. When babies and young children are exposed to heavy toxic metals, the effects can be devastating. "Babies' developing brains are 'exceptionally sensitive to injury caused by toxic chemicals, and several developmental process have been shown to be highly vulnerable to chemical toxicity.'"³ The risk of injury and developmental issues is particularly high in infants due to babies' inability to absorb heavy toxic metals in high amounts. Exposure to heavy toxic metals in early developmental stages can lead to untreatable and permanent brain damage. Studies have shown that exposure to high amounts of lead, for example, can cause IQ loss, brain tumors, and traumatic brain injuries.

³ Ex. 1: Report, at 9.

18. The FDA has declared that inorganic arsenic, lead, cadmium, and mercury can cause severe harmful effects to infants and children and that exposure to these metals can lead to serious illness, severe impairment, and in high doses death. The FDA has cautioned that infants and children face the greatest risk of harm from toxic heavy metal exposure.

19. “Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health . . .”⁴ Arsenic is particularly damaging to the central nervous system and can have devastating effects on cognitive development in children. Boys in particular are more susceptible to arsenic’s neurotoxicity. Studies have shown that exposure to arsenic levels greater than 5 ppb poses a significant threat to cognitive development in young children. In fact, exposure past this “important threshold” leads to decreased global motor, gross motor, and fine motor function scores in young children.

20. Lead is the number two most dangerous substance present in the environment that poses a significant threat to human health. Even small doses of exposure are hazardous to young children and is associated with a broad range of serious health problems. “Lead is associated with a range of bad health outcomes including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth.”⁵ Infants and young children that are exposed to high levels of lead often experience negative neurological effects and decreased brain and nervous system development. Children who have been exposed to lead often suffer from learning disabilities, behavioral disabilities, and low IQ. The cognitive effects of lead exposure to infants and young children are often permanent.

⁴ Ex. 1: Report, at 10.

⁵ Ex. 1: Report, at 11.

21. Cadmium is number seven on the list of dangerous substances present in the environment. Cadmium is associated with IQ loss and development of ADHD. Boys, in particular, suffer higher rates of IQ loss when exposed to high levels of cadmium.

22. Mercury is number three on the list of dangerous substances present in the environment. Higher blood mercury levels in young children has been associated with developmental and cognitive injuries and other behavioral problems.

Hain products contain high levels of arsenic.

23. Inorganic arsenic consumption by babies is unsafe at any level. The FDA has set a maximum inorganic arsenic level of 10 ppb for bottled water. Testing showed that Hain's baby food products contain as much as 129 ppb inorganic arsenic. And that Hain uses ingredients that tested as high as 309 ppb arsenic. Hain also uses a vitamin pre-mix that contains 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic. At least 24 ingredients used by Hain in its organic baby food products tested at more than 100 ppb arsenic. Hain set its own internal standard for arsenic at 200 ppb which allowed it to justify accepting wheat flour and rice that contained between 150-200 ppb arsenic. And Hain's finished baby food products contained more arsenic than the ingredients 100% of the time. In fact, arsenic levels of Hain's finished products were found to be 28-93% higher than the ingredients alone.

Hain products contain high levels of lead.

24. Health experts agree that lead levels in baby food should not exceed 1 ppb. Hain has used ingredients containing as much as 352 ppb lead. A total of 88 ingredients used by Hain tested at levels over 20 ppb lead with six ingredients testing as high as 200 ppb lead. At least 27% of Hain ingredients tested at over 5 ppb lead. And not a single ingredient tested

showed levels below 1 ppb lead. Hain set an internal limit of 200 ppb for lead in five of its ingredients. These levels are 40 times higher than the FDA's guidance for lead ppb in bottled water. These standards surpass every existing regulatory standard for lead.

Hain products contain high levels of cadmium.

25. The World Health Organization has set a standard of 3 ppb cadmium while Consumer Reports advises a limit of 1 ppb cadmium in fruit juices. Testing showed that Hain used ingredients in its baby food products containing up to 260 ppb cadmium. And testing revealed that 102 Hain ingredients tested over 20 ppb cadmium—20 times the level recommended by Consumer Reports.

Hain products contain high levels of mercury.

26. The EPA has capped mercury in drinking water at 2 ppb. Consumer advocates urge even stricter standards for baby food products from companies like Hain. Some groups have called for a goal of no measurable amount of mercury in baby food. From the documents produced to the Subcommittee by Hain, there is no indication that Hain even tests for mercury in its finished products.

Hain distributes its products nationwide, including to Texas Whole Foods stores.

27. Hain distributes and sells its Earth's Best Organic baby food products throughout the country using large retail chains including Whole Foods, Target, Smiths Food and Drug, Walgreens, CVS Pharmacy, and Randalls Food Market. Hain's products are also available through online retailers like Amazon, Instacart, and Walmart.

Plaintiffs purchased Earth's Best products for their son E.P.

28. Dr. Sarah Palmquist, as a board-certified radiologist and Assistant Professor with M.D. Anderson, and Grant Palmquist, as a Logistics Analyst, understand that what a child eats

lays the foundation for their development and their future. Plaintiffs, Sarah and Grant Palmquist, conducted significant research into the food that they would provide their son. After reviewing the products on the market, the Palmquists decided that Earth's Best was the best organic baby food on the market and believed that they were providing their son with the highest quality and safest nutrition possible. Dr. Sarah and Grant Palmquist were loyal Earth's Best customers and purchased these products from Whole Foods.

E.P. consumed primarily Earth's Best products throughout his developmental years.

29. As a newborn infant, E.P. was placed on Earth's Best Organic Dairy Infant Formula with Iron to supplement the breast milk being provided by his mother. From E.P.'s birth until eight months of age, E.P. would consume approximately 2-3 cans of Organic Dairy Infant Formula per month. E.P. drank Earth's Best formula nearly exclusively. At the age of six months, E.P. was introduced to Earth's Best Organic Rice Cereal and then quickly introduced to other Earth's Best baby foods that included Earth's Best Whole Grain Oatmeal Cereal, Earth's Best Whole Grain Oatmeal Cereal, Earth's Best Stage 1 foods, which included Sweet Potatoes, First Peas, First Bananas, First Prunes, First Apples, and First Pears.

30. E.P. was switched fully over to the Earth's Best formula when Dr. Sarah Palmquist had to cease breastfeeding at the age of eight months. At this point, E.P.'s consumption of Earth's Best Organic Dairy Infant Formula increased to 4-5 canisters per month in addition to his eating of the Earth's Best cereals and Stage 1 foods. Shortly after learning to eat Stage 1 foods, E.P. graduated to Stage 2 foods that included Earth's Best Winter Squash, Earth's Best Sweet Potato & Chicken Dinner, Earth's Best Pears & Mangos, Earth's Best Vegetable Turkey Dinner, Earth's Best Spinach & Potato, and Earth's Best Sweet Potatoes. When E.P. was developmentally ready and of age, he again graduated to the next level of foods.

The Earth's Best Stage 3 foods that E.P. ate included Earth's Best Tender Chicken & Stars, Earth's Best Apple Cinnamon Oatmeal, Earth's Best Vegetable Soup, Earth's Best Spring Vegetables & Pasta, Earth's Best Sweet Peas & Creamed Spinach Medley, and Earth's Best Zucchini Broccoli Medley.

31. As E.P. approached ten to eleven months until approximately three years old, E.P. also ate the pouches made by Earth's Best that includes Earth's Best Organic Beef Medley with Vegetables, Earth's Best Organic Chicken Pot Pie, Earth's Best Organic Turkey Quinoa Apple Sweet Potato, Earth's Best Organic Pear Carrot Apricot, and Earth's best Organic Fruit Yogurt Smoothies. Being a toddler, E.P. also devoured snacks, these snacks included Earth's Best Sunny Days Snack Bars (Apple), Earth's Best Organic Garden Veggie Straws, Earth's Best Organic Crunchin' Crackers, and Earth's Best Organic Sunny Days Snack Bars (Strawberry). E.P. consumed Earth's Best baby food nearly exclusively.

***As a result of high levels of toxic metals in his system,
E.P. now suffers from severe brain and bodily injuries.***

32. E.P. was born on September 27, 2014, to Sarah and Grant Palmquist after a healthy and uneventful pregnancy by his mother, Dr. Sarah Palmquist. Following routine postnatal care, E.P. was released home into the care of his parents. E.P. was a healthy, happy, and social baby boy and was excelling at meeting his developmental milestones until shortly before he turned three years old when he began to exhibit symptoms of brain damage. E.P. went from a vibrant, active, and talkative toddler to suffering from concrete and sustained abnormalities that would be diagnosed as brain damage resulting from confirmed heavy metal toxicity. E.P., at the current age of 6, now requires round-the-clock care, is not toilet trained, suffers from gastrointestinal issues, has a significant loss of fine and gross motor skills, has

aggression issues, and is unable to communicate with his parents and caregivers. E.P. requires constant monitoring to ensure that he does not injure himself or elope.

33. In the period between May to August 2017, at 2 years and 8 months old, E.P. demonstrated a rapid regression in all areas of development. The loquacious two-year-old was now unable to communicate and became clumsy, slow, and demonstrated severely regressed gross and fine motor function. E.P. additionally developed chronic diarrhea which often occurred up to 6-8 times per day, and a severely bloated stomach.

34. From August 2017 through December 2017, Plaintiffs Sarah and Grant Palmquist, visited with several doctors and therapists in an attempt to diagnose, treat, and manage the rapid regression that E.P. was experiencing. In December 2017, the Palmquists consulted with a developmental pediatrician with MAPS (Medical Academy of Pediatric Special Needs) certification. After taking an extensive clinical history, evaluating, and observing, E.P., the doctor initiated a medical workup that included testing for heavy metal toxicity, standard bloodwork, MTHFR genetic variant analysis and a stool sample. The two tests ordered to evaluate for heavy metal toxicity were a hair sample, which analyzes the amount of excreted heavy metals, and a urine porphyrins test, which analyzes ratios of abnormal porphyrins excreted in the urine. In a urine porphyrin test, the presence and concentration of various abnormal porphyrins correspond to levels of heavy metals in the body.

35. E.P. was found to have severe heavy metal toxicity. Both tests showed a high level of heavy metals, notably greater than the 99th percentile on the hair test. The doctor said that it was one of the worst cases the doctor had ever seen. At this time, the reports of high metal toxicity in Earth's Best baby foods were not known to the general public. To address the heavy metal toxicity, the doctor recommended low-dose frequent oral chelation. A method of chelation

that involves taking a low-dose oral chelator based on the patient's weight and is taken at 4-hour intervals for 72 hours, followed by 4 days off. This low-dose chelation method continued for months where E.P.'s family members were required to wake every few hours three days a week to administer the medication. E.P. then started transdermal chelation for continued efforts to lower E.P.'s heavy metal load.

36. The stool test demonstrated an abnormal bacterial overgrowth of yeast and Clostridia bacteria. Plaintiffs were told that the presence of heavy metal toxicity can result in gastrointestinal tract dysbiosis. For this dysbiosis, or microbial imbalance, E.P. was treated with antibiotics and antifungals for three months and then placed on maintenance medication.

37. In December 2017, Plaintiffs, Dr. Sarah Palmquist and Grant Palmquist, requested a 23-hour electroencephalogram (EEG) to rule out a seizure disorder as the reason for E.P.'s unexplained regression. Plaintiffs were aware that sometimes seizure activity can be present without the typical clinical presentations and that sometimes the only symptom is the loss of language. This EEG was interpreted as negative for a seizure disorder. Again, the Plaintiffs were left without a diagnosis for their son's decline and extreme heavy metal toxicity.

38. E.P. was again tested for heavy metals with a urine porphyrin test in August 2018, and again E.P. demonstrated an extremely high toxic load. The physician who ordered the test is another MAPS physician who specializes in pediatric acute onset neuropsychiatric syndrome. The doctor stated that it was one of the worst cases he had ever seen and was baffled by the high load of heavy metals and that he was "loaded with mercury." Blood work was ordered by another of E.P.'s treating physicians to test for infectious or autoimmune causes for epilepsy. Again, no other definitive cause of E.P.'s severe toxic heavy metal load was found.

39. Further testing and treatment that Plaintiffs endured in their search for a cause of E.P.'s brain damage and developmental regression included whole exome genetic sequencing ordered by a pediatric neurologist. This genetic sequencing was ordered on E.P., as well as Dr. Sarah Palmquist and Grant Palmquist. No genetic abnormalities tested for on that exam were found in E.P., Sarah Palmquist, or Grant Palmquist. The doctor performed additional testing, and this included genetic testing for chromosomal deletions and translocations, inherited mitochondrial disorders, and metabolic disorders; all of which were negative. Due to newly discovered genetic mutations, in January 2021, an additional query was made on E.P.'s genetic data and this too was negative.

40. In April 2019, another 23-hour EEG was ordered after E.P. developed a further loss of language after the age of 3 in combination with Sarah Palmquist witnessing what she thought may be signs of a clinical seizure, notably uncontrollable writhing movements on the floor as well as abnormal movements of the facial muscles. The April 2019 EEG was abnormal, consistent with diffuse bilateral frontotemporal epileptiform discharges, diffuse slowing, and mild encephalopathy. This result of the EEG was not consistent with any known childhood epilepsy disorder. Research demonstrates that heavy metal toxicity can induce seizures. E.P. was then placed on an anti-epileptic drug in which he remains on today. During the time seizure activity was suspected by Dr. Sarah Palmquist and treatment for seizures was initiated, chelation therapy was stopped for safety reasons. Once the seizures were diagnosed and treated with anti-epileptic medication, E.P. had a follow-up EEG that demonstrated no seizure activity in September 2019. Chelation was reinitiated until treatment was started for his gastrointestinal injuries.

41. From September 2019 through December 2019, Plaintiffs consulted with two physicians specializing in gastrointestinal (GI) disorders in children. These doctors were able to diagnose diffuse inflammation throughout the GI tract. While E.P. was initially placed on a systemic steroid and saw improvement in his GI issues, steroids are not a long-term answer to a chronic injury. Effort was then turned to healing his GI tract since a large portion of detoxification occurs through the bile excreted from the liver. E.P. was placed on several antibiotics to eradicate the dysbiotic bacteria, and then high doses of probiotics. After treatment, some of E.P.'s GI issues have improved in terms of consistency and frequency of bowel movements. However, the brain damage resulting in profound developmental delay and intellectual impairment remains.

42. Extensive diagnostic testing, including lab work, genetic sequencing, EEGs, a brain MRI, and expert clinical assessment by multiple physicians have ruled out numerous potential other causes of E.P.'s brain damage. Abnormal pregnancy, birth trauma, genetic causes, structural brain abnormalities, childhood epilepsy disorder, metabolic, and infectious causes have also been excluded. Further, E.P. has never experienced trauma to his head nor any other region of his body. While some of E.P.'s gastrointestinal issues have improved, E.P. remains profoundly brain damaged. E.P. functions at the level of a child aged two years or younger. His communication skills are in the <1 percentile for his age and he is not even able to undergo IQ testing due to his severe impairments. Numerous peer reviewed authoritative articles have evidenced the association between brain damage and GI issues in infants when chronically exposed to heavy metals in infancy. E.P. has been irreparably harmed from his chronic heavy metal exposure during his pivotal development as an infant and young child due to Earth's Best baby formula and baby food.

VII.

CAUSES OF ACTION

A. Negligence against All Defendants

43. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

44. Plaintiffs were injured because of Defendants' negligence and gross negligence when Defendants negligently:

- a. designed, produced, marketed, and distributed baby food products with dangerous levels of heavy toxic metals;
- b. failed to warn Plaintiffs regarding the dangerous amounts of heavy toxic metals present in Hain's Earth's Best Organic baby food products;
- c. failed to properly label its products knowing that the products contained dangerous levels of heavy toxic metals;
- d. failed to comply with applicable standards, rules, and regulations regarding safe levels of arsenic, lead, cadmium, and mercury;
- e. failed to adequately test its ingredients and its final products for dangerous levels of heavy toxic metals;
- f. committed other acts deemed negligent and grossly negligent.

45. Defendants owed Plaintiffs a duty to provide safe products and to adequately warn them of the levels of heavy toxic metals contained in those products. As outlined above, Defendants breached those duties. These breaches were both the cause in fact and proximate cause of Plaintiffs' injuries. As a result of Defendants' negligence, Plaintiff E.P.

sustained severe injuries to his body, including severe brain damage and neurological injuries from which he will never fully recover. His injuries have resulted in physical pain, mental anguish, and other medical problems. Plaintiffs Grant and Sarah Palmquist have suffered severe pain, mental anguish, and emotional distress due to their son's injuries. Plaintiffs have incurred and will continue to incur pharmaceutical and medical expenses in connection with E.P.'s injuries. Plaintiffs are entitled to recover for their injuries. Defendants' actions were done with reckless disregard to a substantial risk of bodily injury. Accordingly, Plaintiffs are entitled to punitive damages.

46. Furthermore, Plaintiffs are entitled to punitive damages because Defendants' actions were grossly negligent. Defendants acted with flagrant and malicious disregard for Plaintiff E.P.'s health and safety. Defendants knew the extreme risks posed by the high levels of heavy toxic metals in their baby food products but ignored those risks and intentionally sold the products knowing of the dangers to babies and children like Plaintiff. Further, Defendants failed to warn Plaintiffs of the extreme risk and hazard Earth's Best Organic baby foods posed to Plaintiff. Defendants had actual, subjective awareness of the risk and consciously disregarded such risk by allowing Plaintiffs to buy the Earth's Best Organic products and to feed them to E.P. Defendants knew consumers like Plaintiffs would rely on Hain's claims, purchase the baby food based on those claims, and feed it to children like E.P. These acts were willful, wanton, and grossly negligent.

B. Products Liability against The Hain Celestial Group, Inc.

47. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

48. Plaintiffs are "persons" as defined in Texas Business and Commerce Code

§ 17.45(3).

49. As defined in Texas Business and Commerce Code §§ 17.45(9) and (13), Hain knowingly and intentionally engaged in false, misleading, and deceptive acts that caused Plaintiffs' injuries.

50. Specifically, Hain knowingly, that is with actual awareness of the falsity, deception, and unfairness of its acts, sold its Earth's Best Organic baby food products with high, dangerous levels of heavy toxic metals. Hain intentionally did so with the specific intent that Plaintiffs would act in detrimental reliance on the falsity or deception or in detrimental ignorance of the unfairness of Hain's claims. Plaintiffs bought and fed E.P. Hain's Earth's Best Organic baby food products almost exclusively due to them being widely available and due to Hain's claims that its products were high quality and safe. E.P.'s injuries are a direct result of Hain's deceptive practices.

51. Further, Hain designed, tested, manufactured, marketed, distributed, and/or sold its Earth's Best baby food products with design, manufacturing, and/or marketing defects.

52. **Manufacturing Defect:** Hain's baby food products were designed, manufactured, distributed, and/or sold with one or more manufacturing defects. Specifically:

- a. Hain provided its products to consumers like Plaintiffs in a defective condition with high levels of heavy toxic metals that rendered the products unreasonably dangerous and unsafe for use by babies and small children;
- b. Hain's products deviated in quality from suggested industry standards and were produced with ingredients that contained high toxic levels of

arsenic, lead, cadmium, and mercury;

- c. Hain failed to properly test its final products to ensure that the levels of heavy toxic metals contained in them were below levels established by applicable regulations and accepted by industry standards;
- d. When the products left Hain's custody or control they had been manufactured defectively;
- e. The design, manufacturing, and/or marketing defects rendered the baby food products in question unreasonably dangerous.

53. The manufacturing defects that rendered the baby food products unreasonably dangerous were the producing, proximate, and contributing cause of Plaintiffs' injuries.

54. **Design Defect:** Hain's Earth's Best baby food products were designed, manufactured, distributed, and sold with one or more design defects.

- a. Hain designed its Earth's Best Organic baby food products in an unreasonably dangerous manner while safer alternative designs were available at the time of the design and production of the food products in question. Specifically, Hain used ingredients that contained high levels of heavy toxic metals that were not removed during production. Better, safer ingredients were available for Hain to use in its products.
- b. Hain either knew or should have known that safer ingredients were available that would reduce the level of heavy toxic metals in their final products to levels that are considered safe by health experts and that comply with federal regulations and industry standards.
- c. The safer alternative designs would have prevented or significantly

reduced the previously mentioned risks without substantially impairing the products. In fact, had Hain used safer ingredients it would have served the purpose of ensuring that the final products matched the claims Hain made about them.

- d. The safer alternative design was economically and technologically feasible at the time the baby food products left Hain's control. Safer ingredients are readily available as are testing methods to ensure the safety of the baby food products.
- e. Hain either knew or should have known that the design, manufacturing, and marketing defects deviated from the planned specifications for the baby food products in question.
- f. The design defects rendered the baby food products unreasonably dangerous.

55. The baby food products' defective design was the producing, proximate, and contributing cause of Plaintiffs' injuries.

56. **Marketing Defects and Failure to Warn:** The baby food products in question were designed, manufactured, distributed, and sold with one or more marketing defects.

- a. There was an unreasonable risk in the intended or reasonably foreseeable use of Hain's Earth's Best Organic baby food products. Specifically,
- b. Hain failed to adequately warn Plaintiffs of the risk relating to feeding their child baby food containing high levels of heavy toxic metals.

Specifically, Hain did not provide adequate warning labels indicating that consuming the baby food products could cause severe neurological injuries. Hain failed to instruct Plaintiffs regarding the risks and failed to instruct Plaintiffs on how to avoid the dangers.

- c. Including appropriate warnings and providing complete information regarding the contents of its products would have been both technologically and economically feasible for Hain when the products left its custody and control.
- d. The marketing defects rendered the baby food products unreasonably dangerous.

57. Hain's failure to warn and the marketing defects relating to the products in question were the producing, proximate, and contributing cause of Plaintiffs' injuries.

58. As a direct and proximate result of Hain's conduct, Plaintiff E.P. sustained severe injuries to his body and mind that resulted in severe, permanent cognitive and neurological injuries, physical pain, mental anguish, and other medical problems. E.P. will never fully recover from his injuries and will continue to suffer the debilitating effects of his neurological injuries throughout the remainder of his life. E.P. will be severely limited and unable to function normally. Additionally, Plaintiffs Grant and Sarah Palmquist have suffered mental anguish, emotional trauma, and financial loss due to E.P.'s injuries. Plaintiffs have incurred and will continue to incur pharmaceutical and medical expenses in connection with E.P.'s injuries.

59. Plaintiffs are also entitled to exemplary damages because of Hain's actions and inactions. Hain's conduct rises to the level of gross negligence. Hain was subjectively

aware that its baby food products contained high levels of heavy toxic metals and were subjectively aware that these neurotoxins would likely injure infants and young children. Hain's actions and inactions when viewed objectively, subjected Plaintiffs to an extreme degree of risk.

C. Breach of Warranties against Whole Foods Market Rocky Mountain/Southwest, L.P.

60. Plaintiffs incorporate by reference the facts and allegations of the preceding paragraphs.

61. Whole Foods Market Rocky Mountain/Southwest, L.P. ("Whole Foods") sold Hain's Earth's Best Organic baby food products and in doing so impliedly warranted to the public generally and specifically that the products were safe for consumption by infants and young children.

62. Whole Foods knew or had reason to know that consumers like Plaintiffs would purchase the Hain products due to their being advertised as safe and high-quality organic baby food.

63. Whole Foods' implied warranty was incorrect given the high levels of heavy toxic metal Hain's baby food products contained.

64. Plaintiffs relied on Whole Foods' representations that Hain's Earth's Best Organic baby food products were safe and of the highest quality.

65. If Hain's products were as advertised, Plaintiffs would not have been injured by the product. Hain and Whole Foods markets the Earth's Best Organic baby food products as safe, natural, and organically produced. If the products had been in a condition as advertised, E.P. would not have been exposed to extremely high, toxic levels of arsenic, lead, cadmium, and mercury and would not have suffered cognitive brain injuries as a result.

66. Plaintiffs' injuries were sustained because of Whole Foods' implied warranties.

VIII.

DAMAGES

67. Plaintiffs seek damages in excess of \$1,000,000.00. Specifically, as a direct and proximate result of Defendants' acts and omissions, Plaintiff E.P. has suffered serious, permanent, and disabling injuries. As a further result of such injuries, Plaintiff has also suffered physical pain, discomfort, disfigurement, physical impairment and extraordinary emotional pain and mental anguish. Plaintiff will continue to suffer such damages into the future, if not for the balance of his natural life.

68. In addition, as a direct and proximate result of Defendants' acts and omissions, Plaintiffs Grant and Sarah Palmquist have incurred reasonable and necessary medical and healthcare expenses, which expenses will continue to be incurred in the future. All of these damages which have been suffered by Plaintiffs herein have a monetary value which greatly exceeds the minimum jurisdictional limits of this Court. Plaintiffs pray for relief and judgment as follows:

- Compensatory damages against Defendants;
- Actual damages;
- Loss of services and earnings of an un-emancipated minor;
- Consequential damages;
- Pain and suffering;
- Exemplary damages;

- Past and future mental anguish;
- Past and future impairment;
- Past and future disfigurement;
- All other damages allowable under Texas law;
- Interest on damages (pre and post-judgment) in accordance with the law;
- Costs of Court;
- Expert witness fees;
- Costs of copies of depositions; and
- Such other and further relief as the Court may deem just and proper.

IX.

JURY TRIAL DEMANDED

69. Plaintiffs hereby request a trial by jury on all claims and submit their jury fee herewith.

X.

PRAYER

Plaintiffs pray that this citation issue and be served upon Defendants in a form and manner prescribed by law, requiring that Defendants appear and answer, and that upon final hearing, Plaintiffs have judgment against Defendants in a total sum in excess of the minimum jurisdictional limits of this Court, pre-judgment and post-judgment interests, all costs of Court, exemplary damages, and all such other and further relief, to which they may show themselves justly entitled.

Respectfully Submitted,

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ATTORNEYS FOR PLAINTIFFS

EXHIBIT 1



Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury



Staff Report

**Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives**

February 4, 2021

oversight.house.gov

EXECUTIVE SUMMARY

Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The Food and Drug Administration and the World Health Organization have declared them dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects. Even low levels of exposure can cause serious and often irreversible damage to brain development.

On November 6, 2019, following reports alleging high levels of toxic heavy metals in baby foods, the Subcommittee on Economic and Consumer Policy requested internal documents and test results from seven of the largest manufacturers of baby food in the United States, including both makers of organic and conventional products:

- Nurture, Inc. (Nurture), which sells Happy Family Organics, including baby food products under the brand name HappyBABY
- Beech-Nut Nutrition Company (Beech-Nut)
- Hain Celestial Group, Inc. (Hain), which sells baby food products under the brand name Earth's Best Organic
- Gerber
- Campbell Soup Company (Campbell), which sells baby food products under the brand name Plum Organics
- Walmart Inc. (Walmart), which sells baby food products through its private brand Parent's Choice
- Sprout Foods, Inc. (Sprout Organic Foods)

Four of the companies—Nurture, Beech-Nut, Hain, and Gerber—responded to the Subcommittee's requests. They produced their internal testing policies, test results for ingredients and/or finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits.

Walmart, Campbell, and Sprout Organic Foods refused to cooperate with the Subcommittee's investigation. The Subcommittee is greatly concerned that their lack of cooperation might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

FINDINGS

1. According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function. Specifically, the Subcommittee reports that:

ARSENIC was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.
- Hain (Earth's Best Organic) sold finished baby food products containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic.
- Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as "crumb softness."
- Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

LEAD was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.
- Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.
- Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.
- Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.

CADMIUM was present in baby foods made by all responding companies.

- Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.
- Hain (Earth's Best Organic) used 102 ingredients in its baby food that tested over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.

- Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium.
- Seventy-five percent of Gerber's carrots contained cadmium in excess of 5 ppb, with some containing up to 87 ppb cadmium.

MERCURY was detected in baby food of the only responding company that tested for it.

- Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.
- Beech-Nut and Hain (Earth's Best Organic) do not even test for mercury in baby food.
- Gerber rarely tests for mercury in its baby foods.

These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level.

2. Internal company standards permit dangerously high levels of toxic heavy metals, and documents revealed that the manufacturers have often sold foods that exceeded those levels.
 - Nurture (HappyBABY) sold all products tested, regardless of how much toxic heavy metal the baby food contained. By company policy, Nurture's toxic heavy metal testing is not intended for consumer safety. The Food and Drug Administration (FDA) has only finalized one standard—100 ppb inorganic arsenic in infant rice cereal—and Nurture set its internal standard for that product 15% higher than the FDA limit, at 115 ppb.
 - Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.
 - Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified deviations above its ingredient testing

standards based on “theoretical calculations,” even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

3. The Subcommittee has grave concerns about baby food products manufactured by Walmart (Parent’s Choice), Sprout Organic Foods, and Campbell (Plum Organics). These companies refused to cooperate with the Subcommittee’s investigation. The Subcommittee is greatly concerned that their lack of cooperation might obscure the presence of even higher levels of toxic heavy metals in their baby food products, compared to their competitors’ products.
 - Walmart sells Parent’s Choice and Parent’s Choice Organic products for babies as young as four months.
 - Sprout Organic Foods sells organic products for babies as young as six months. It is owned by North Castle Partners, a Greenwich, Connecticut–based private equity firm.
 - Campbell sells Plum Organics products for babies as young as four months.
 - Independent testing of Walmart, Sprout Organic Foods, and Campbell products has confirmed that their baby foods contain concerning levels of toxic heavy metals.
4. The Trump administration ignored a secret industry presentation to federal regulators revealing increased risks of toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain (Earth’s Best Organic), which revealed that:
 - Corporate policies to test only ingredients, not final products, underrepresent the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and 93% higher in the finished products;
 - Many of Hain’s baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic; and
 - Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Hain may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

This presentation made clear that ingredient testing is inadequate, and that only final product testing can measure the true danger posed by baby foods.

The Trump FDA took no new action in response. To this day, baby foods containing toxic heavy metals bear no label or warning to parents. Manufacturers are free to test only ingredients, or, for the vast majority of baby foods, to conduct no testing at all. FDA has only finalized one metal standard for one narrow category of baby food, setting a 100 ppb inorganic arsenic standard for infant rice cereal. But this FDA standard is far too high to protect against the neurological effects on children.

5. The Subcommittee makes the following recommendations:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice;
- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

6. Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and the Trump administration's federal regulators have broken the faith.

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I. THE DANGER OF TOXIC HEAVY METALS TO CHILDREN'S HEALTH

Children's exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior.¹

Babies' developing brains are "exceptionally sensitive to injury caused by toxic chemicals, and several developmental processes have been shown to be highly vulnerable to chemical toxicity."² The fact that babies are small, have other developing organ systems, and absorb more of the heavy metals than adults, exacerbates their risk from exposure to heavy metals.³

Exposure to heavy metals at this developmental stage can lead to "untreatable and frequently permanent" brain damage, which may result in "reduced intelligence, as expressed in terms of lost IQ points, or disruption in behavior."⁴ For example, a recent study estimates that exposure to environmental chemicals, including lead, are associated with 40,131,518 total IQ points loss in 25.5 million children (or roughly 1.57 lost IQ points per child)—more than the total IQ losses associated with preterm birth (34,031,025), brain tumors (37,288), and traumatic brain injury (5,827,300) combined.⁵ For every one IQ point lost, it is estimated that a child's lifetime earning capacity will be decreased by \$18,000.⁶

Well-known vectors of child exposure to toxic heavy metals include lead paint in old housing and water pollution from landfills. Over the decades, a range of federal and state laws and regulations have been passed to protect child health through emissions standards, among other things.

The Food and Drug Administration (FDA) has declared that inorganic arsenic, lead, cadmium, and mercury are dangerous, particularly to infants and children. They have "no established health benefit" and "lead to illness, impairment, and in high doses, death." According to FDA, "even low levels of harmful metals from individual food sources, can

¹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

² Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

³ Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018) (online at www.consumerreports.org/food-safety/heavy-metals-in-baby-food/).

⁴ Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

⁵ David C. Bellinger, *A Strategy for Comparing the Contributions of Environmental Chemicals and Other Risk Factors to Neurodevelopment of Children* (Dec. 19, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/).

⁶ Martine Bellanger et al., *Economic Benefits of Methylmercury Exposure Control in Europe: Monetary Value of Neurotoxicity Prevention* (Jan. 17, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23289875/>).

sometimes add up to a level of concern.” FDA cautions that infants and children are at the greatest risk of harm from toxic heavy metal exposure.⁷

The Subcommittee on Economic and Consumer Policy’s investigation has found another source of exposure: baby foods. According to documents obtained from baby food manufacturers, toxic heavy metals, such as arsenic, cadmium, lead, and mercury are present at substantial levels in both organic and conventional baby foods. Currently, there is no federal standard on, or warning to parents and caregivers about, these toxins.

A. Inorganic Arsenic

Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health, according to the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (ATSDR).⁸ The known health risks of arsenic exposure include “respiratory, gastrointestinal, haematological, hepatic, renal, skin, **neurological and immunological effects, as well as damaging effects on the central nervous system and cognitive development in children.**”⁹

Studies have concluded that arsenic exposure has a “significant negative effect on neurodevelopment in children.”¹⁰ This negative effect is most pronounced in Full Scale IQ, and more specifically, in verbal and performance domains as well as memory. For every 50% increase in arsenic levels, there is an approximately “0.4 decrease in the IQ of children.”¹¹

A study of Maine schoolchildren exposed to arsenic in drinking water found that children exposed to water with an arsenic concentration level greater than 5 parts per billion (ppb) “showed significant reductions in Full Scale IQ, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.” The authors pegged 5 ppb as an important threshold.¹²

Likewise, a study of children in Spain found that increasing arsenic exposure led to a decrease in the children’s global motor, gross motor, and fine motor function scores. Boys in particular were more susceptible to arsenic’s neurotoxicity.¹³

⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

⁸ Agency for Toxic Substances and Disease Registry, *ATSDR’s Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

⁹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (June 1, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23570911/>) (emphasis added).

¹⁰ *Id.*

¹¹ *Id.*

¹² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹³ Antonio J. Signes-Pastor et al., *Inorganic Arsenic Exposure and Neuropsychological Development of Children of 4-5 Years of Age Living in Spain* (Apr. 29, 2019) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/).

B. Lead

Lead is number two on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.¹⁴ Even small doses of lead exposure are hazardous, particularly to children.¹⁵ Lead is associated with a range of bad health outcomes, including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth. According to FDA, lead is especially dangerous to "infants" and "young children." FDA acknowledges that:

High levels of lead exposure can seriously harm children's health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹⁶

Lead exposure severely affects academic achievement in children. Even at low levels, early childhood lead exposure has a negative impact on school performance. Two separate studies of schoolchildren in Detroit and Chicago public schools found a strong inverse relationship between lead exposure and test scores. In the Detroit study, there was a "significant association" between early childhood lead exposure and decreased standardized test performance, with lead exposure strongly linked to an adverse effect on academic achievement.¹⁷ The Chicago study found that higher blood lead concentrations were associated with lower reading and math scores in 3rd grade children. Increased blood lead concentrations correlated with a 32% increase in the risk of failing reading and math.¹⁸

The cognitive effects of early childhood lead exposure appear to be permanent. In one study, adults who previously had lead-associated developmental delays continued to show persisting cognitive deficits, demonstrating the long-lasting damage of lead exposure.¹⁹

¹⁴ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

¹⁵ Philippe Grandjean, *Even Low-Dose Lead Exposure Is Hazardous* (Sept. 11, 2010) (online at <https://pubmed.ncbi.nlm.nih.gov/20833288/>).

¹⁶ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹⁷ Nanhua Zhang et al., *Early Childhood Lead Exposure and Academic Achievement: Evidence From Detroit Public Schools* (Mar. 2013) (online at <http://mediad.publicbroadcasting.net/p/michigan/files/201302/AJPH.2012.pdf>).

¹⁸ Anne Evens et al., *The Impact of Low-Level Lead Toxicity on School Performance Among Children in the Chicago Public Schools: A Population-Based Retrospective Cohort Study* (Apr. 7, 2015) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0008-9>).

¹⁹ Maitreyi Mazumdar et al., *Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-Up Study* (Mar. 30, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/).

Studies have also established a significant association between lead exposure and Attention-Deficit/Hyperactivity Disorder (ADHD).²⁰

C. Cadmium

Cadmium is number seven on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²¹ Cadmium is associated with decreases in IQ, as well as the development of ADHD.

A 2018 study found that cadmium exposure negatively affected children's Full Scale IQ, particularly among boys. Boys exhibiting higher amounts of cadmium exposure had seven fewer IQ points than those exhibiting less cadmium exposure.²² A 2015 study similarly found a significant inverse relationship between early cadmium exposure and IQ.²³

A 2018 study linked cadmium exposure to ADHD, finding that the disorder was more common among children with the highest levels of cadmium exposure as compared to a control group.²⁴

D. Mercury

Mercury is number three on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²⁵ Studies of mercury's effect on childhood development have primarily been conducted by considering the mother's exposure to mercury while pregnant. In these instances, "pre-natal mercury exposure has been consistently associated with adverse subsequent neuro-development."²⁶ And pre-natal mercury exposure is also related to poorer estimated IQ.²⁷ Beyond prenatal exposure, higher blood mercury levels at

²⁰ Gabriele Donzelli et al., *The Association Between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review* (Jan. 29, 2019) (online at www.mdpi.com/1660-4601/16/3/382/htm).

²¹ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²² Klara Gustin et al., *Cadmium Exposure and Cognitive Abilities and Behavior at 10 Years Off Age: A Prospective Cohort Study* (Apr. 2018) (online at www.sciencedirect.com/science/article/pii/S0160412017321025).

²³ Alison P. Sanders et al., *Perinatal and Childhood Exposure To Cadmium, Manganese, And Metal Mixtures And Effects On Cognition And Behavior: A Review Of Recent Literature* (July 5, 2015) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/).

²⁴ Min-Jing Lee et al., *Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony* (June 10, 2018) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/).

²⁵ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²⁶ Margaret R. Karagas et al., *Evidence on the Human Health Effects of Low-Level Methylmercury Exposure* (June 1, 2012) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1104494>).

²⁷ Joseph Jacobson et al., *Relation of Prenatal Methylmercury Exposure from Environmental Sources to Childhood IQ* (Aug. 1, 2015) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1408554>).

“2 and 3 years of age were positively associated with autistic behaviors among preschool-age children.”²⁸

II. TOP BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF INORGANIC ARSENIC, LEAD, CADMIUM, AND MERCURY.

Internal company test results obtained by the Subcommittee confirm that all responding baby food manufacturers sold baby foods tainted by high levels of toxic heavy metals.

A. Inorganic Arsenic

There is no established safe level of inorganic arsenic consumption for babies. Organizations such as Healthy Babies Bright Futures have called for a goal of no measurable amount of inorganic arsenic in baby food.²⁹ Consumer Reports suggests setting inorganic arsenic levels as low as 3 parts per billion (ppb).³⁰ FDA has already set maximum inorganic arsenic levels at 10 ppb for bottled water.³¹ The Environmental Protection Agency (EPA) has similarly set a 10 ppb inorganic arsenic cap on drinking water, as have the European Union (EU) and the World Health Organization (WHO).³²

1. Nurture (HappyBABY) sold finished baby foods after testing showed they contained as much as 180 ppb inorganic arsenic; over 25% of the tested baby food sold by Nurture exceeded 100 ppb inorganic arsenic; on average, Nurture baby food on store shelves has nearly 60 ppb inorganic arsenic.

Nurture is the only baby food manufacturer that appears to regularly tests its finished baby food products for inorganic arsenic content (the others only test ingredients).

²⁸ Jia Ryu et al., *Associations of Prenatal and Early Childhood Mercury Exposure with Autistic Behaviors at 5 Years of Age: The Mothers and Children's Environmental Health (MOCEH) Study* (Dec. 15, 2017) (online at www.sciencedirect.com/science/article/pii/S0048969717316479).

²⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

³⁰ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

³¹ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

³² Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.³³ An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb.

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁴

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	180	ppb	11/01/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17 Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

Nurture routinely sold products that exceeded its internal standards. Twenty-nine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb.³⁵

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁶

Product Name	Goal Threshold	Result	Date of Test Report	Disposition
Apple & Broccoli Puffs	100	180	11/01/17	Sell
Banana & Pumpkin Puffs	100	160	10/31/17	Sell
Strawberry & Beet Puffs	100	160	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Purple Carrot & Blueberry Puffs	100	150	11/17/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Sweet Potato & Carrot Puffs	100	122	09/13/18	Sell
Apple Rice Cakes	100	120	02/08/17	Sell

³³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

Blueberry Beet Rice Cakes	100	120	02/08/17	Sell
Purple Carrot & Blueberry Puffs	100	120	10/31/17	Sell
Apple & Broccoli Puffs	100	115	10/15/18	Sell
Strawberry & Beet Puffs	100	114	03/21/19	Sell
Purple Carrot & Blueberry Puffs	100	112	06/05/18	Sell
Apple Rice Cakes	100	110	07/28/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Strawberry & Beet Puffs	100	108	12/10/18	Sell
Strawberry & Beet Puffs	100	108	09/21/18	Sell
Apple & Broccoli Puffs	100	107	05/30/19	Sell
Strawberry & Beet Puffs	100	107	05/22/19	Sell
Strawberry & Beet Puffs	100	105	09/21/18	Sell
Strawberry & Beet Puffs	100	104	08/22/18	Sell
Banana & Pumpkin Puffs	100	103	04/24/19	Sell
Sweet Potato & Carrot Puffs	100	103	04/24/19	Sell
Banana & Pumpkin Puffs	100	101	09/21/18	Sell

The average amount of inorganic arsenic in the baby foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb.

At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above.

For results under 9.54 ppb, Nurture did not differentiate—it marked them all as “<9.54.” Because of this “less than” reporting format, there is no way to know if any of Nurture's products were free of inorganic arsenic.

Summary of Nurture's Inorganic Arsenic Results

180 ppb – Nurture's product with the highest amount of inorganic arsenic: Apple & Broccoli Puffs.
>100 ppb – Over 25% of the baby food products that were tested for inorganic arsenic had over 100 ppb inorganic arsenic.
59.54 ppb – Average amount of inorganic arsenic in all baby food products tested for inorganic arsenic.
>50 ppb – Over 50% of Nurture's baby food products that were tested for inorganic arsenic contained over 50 ppb inorganic arsenic.

2. **Hain (Earth's Best Organic) produced finished baby foods that contained as much as 129 ppb inorganic arsenic; Hain used ingredients in its baby foods with as much as 309 ppb total arsenic.**

Hain does not regularly test finished baby food products for inorganic arsenic content. It typically only tests ingredients. However, when Hain did test a small sample of finished product, it found 129 ppb inorganic arsenic.³⁷

Hain Celestial, FDA Testing Result Investigation, August 1, 2019 (Excerpted Entries)³⁸

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN 12216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

The Subcommittee's review of the ingredient test results reveals that Hain routinely used ingredients with high levels of arsenic. Hain used brown rice flour that had tested at 309 ppb arsenic.³⁹ Hain likewise used a vitamin pre-mix containing 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.⁴⁰ The testing data shows that Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its already-dangerously-high internal standard for most ingredients.⁴¹

Hain, Raw Material Pre-Shipment Test Data History (Excerpted Entries)⁴²

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Jun/19/2019	Org Brown Rice Flour	Deviation Approved	100	309
Nov/26/2019	Vitamin Pre-Mix	Deviation Approved	100	223
Jul/10/2018	Org Whole Raisins	Accepted	100	200
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Dec/14/2017	Org Spelt Flour	Accepted	100	190
Jan/8/2018	Organic Barley Malt Extract	Accepted	100	180
Dec/5/2017	Org Yellow Split Pea Powder	Accepted	100	160
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150
Oct/3/2017	Org Brown Rice Flour	Accepted	100	140
Sep/4/2019	Org Brown Rice Flour	Deviation Approved	100	134
Dec/5/2017	Org Butternut Squash Puree	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	130

³⁷ Hain, *PowerPoint Presentation to FDA: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

³⁸ *Id.*

³⁹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

Oct/31/2017	Org Brown Rice Flour	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	127
Oct/31/2017	Org Brown Rice Flour	Accepted	100	126
Dec/13/2017	Org Blueberry Puree	Accepted	100	120
Dec/27/2017	Org Barley Flour	Accepted	100	120
Oct/31/2017	Org Brown Rice Flour	Accepted	100	119
Nov/29/2017	Org Blueberry Puree	Accepted	100	110
Nov/3/2017	Org Cinnamon Powder	Accepted	100	110
Jul/11/2019	Org Brown Rice Flour	Accepted	100	101

3. Beech-Nut used ingredients in its baby foods with as much at 913.4 ppb arsenic; Beech-Nut routinely used ingredients that exceeded 300 ppb total arsenic; Beech-Nut unnecessarily uses high-arsenic additives to address issues like “crumb softness.”

Beech-Nut only tested arsenic content in its ingredients, not its final product. The Subcommittee has determined that Beech-Nut used ingredients containing as much as 913.4 ppb arsenic.⁴³ Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic.⁴⁴ And it used at least 45 ingredients containing over 100 ppb arsenic.

Beech-Nut, Raw Material Heavy Metal Testing (Excerpted Entries)⁴⁵

Date	Commodity	Arsenic Result (ppb)	Spec.	Acceptance (Y/N)
9/19/2018	Amylase	913.40	N/A	Y
4/26/2018	Amylase	741.10	N/A	Y
10/7/2017	BAN 800	710.90	<3000	Y
11/29/2017	Alpha Amylase	679.00	N/A	Y
10/12/2017	Amylase	645.10	N/A	Y
8/20/2019	Sebamyl 100	583.60	N/A	Y
3/6/2018	Org. Rice Flour	570.00	≤100(inorg)	Y
6/7/2019	Enzyme	499.30	N/A	Y
12/20/2017	BAN 800	465.20	<3000	Y
1/14/2019	Enzyme	442.30	N/A	Y
10/23/2017	BAN 800	401.40	<3000	Y

⁴³ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁴⁴ *Id.*

⁴⁵ *Id.*

2/19/2018	BAN 800	382.00	<3000	Y
6/12/2018	Ban 800	353.80	<3000	Y
5/21/2018	Org. Cumin	322.70	≤1000	Y
4/13/2018	Org. Rice	237.40	≤100(inorg)	Y
4/12/2018	Rice Flour	170.00	≤100(inorg)	Y
4/6/2018	Rice Flour	170.00	≤100(inorg)	Y
7/14/2017	Org. Cumin	168.50	≤1000	y
7/31/2018	rice flour	162.00	≤100(inorg)	Y
2/28/2018	Rice Flour	161.00	≤100(inorg)	y
3/30/2017	Cumin	160.50	≤1000	Y
3/27/2018	Rice Flour	160.00	≤100(inorg)	Y
5/30/2018	Rice Flour	160.00	≤100(inorg)	Y
6/12/2018	Rice Flour	160.00	≤100(inorg)	Y
7/20/2018	Rice Flour	160.00	≤100(inorg)	Y
10/11/2016	Oregano	158.10	<1000	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
2/15/2018	Rice Flour	150.00	≤100(inorg)	Y
5/31/2018	Rice Flour	150.00	≤100(inorg)	Y
2/22/2018	Rice Flour	140.00	≤100(inorg)	Y
1/6/2018	Rice Flour	140.00	≤100(inorg)	Y
4/6/2018	Rice Flour	140.00	≤100(inorg)	Y
9/4/2019	Org. rice	132.30	≤200	Y
11/3/2017	Org.Cumin	130.20	≤1000	Y
2/15/2018	Rice Flour	130.00	≤100(inorg)	Y
2/5/2018	Rice Flour	130.00	≤100(inorg)	Y
2/8/2018	Rice Flour	130.00	≤100(inorg)	Y
1/5/2018	Rice Flour	122.30	≤100(inorg)	Y
1/5/2018	Rice Flour	120.80	≤100(inorg)	Y
2/8/2018	Rice Flour	120.00	≤100(inorg)	Y
1/18/2017	Org.Rice	110.00	≤200	Y
5/8/2018	Rice Flour	110.00	≤100(inorg)	Y
5/17/2017	Rice	110.00	≤200	Y
2/6/2017	Vitamin Mix	106.90	<3000	Y

The six Beech-Nut ingredients with the highest arsenic levels—Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly “[i]ncreases crumb softness” in baked goods.⁴⁶ Amylase is an

⁴⁶ Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018) (online at www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf).

enzyme that is “used in bread-making as an additive to improve the conversion of complex sugars into simple sugars that yeast are then able to feed on and produce alcohol and CO₂.”⁴⁷

4. Gerber used 67 batches of rice flour that had more than 90 ppb inorganic arsenic.

Gerber did not provide inorganic arsenic results for all of its ingredients. However, test results for conventional rice flour revealed that Gerber routinely used flour with over 90 ppb inorganic arsenic.⁴⁸ Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.

Gerber Products Company Test Results (Excerpted Entries)⁴⁹

Year	Ingredient	Total Arsenic (ppb)	Inorganic Arsenic (ppb)
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96

⁴⁷ ChefSteps, *Amylase* (online at www.chefsteps.com/ingredients/amylase) (accessed Jan. 26, 2021).

⁴⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁴⁹ *Id.*

2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	95	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	94	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	121	93
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	92	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92

2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91

B. Lead

There is a growing consensus among health experts that lead levels in baby foods should not exceed 1 ppb. The American Academy for Pediatrics, the Environmental Defense Fund, and Consumer Reports have all, in some form, called for a 1 ppb level in food and drinks that babies and children consume.⁵⁰ Healthy Babies Bright Futures has called for a goal of no measurable amount of lead in baby food.⁵¹

There is no federal standard for lead in baby food. However, FDA has set a 5 ppb lead standard for bottled water, WHO has set 10 ppb lead as a provisional guideline for drinking water, and EPA has set an action level of 15 ppb for lead in drinking water. FDA has also set standards for lead in juice (50 ppb) and candy (100 ppb). The European Union has set the maximum lead level in infant formula to 20 ppb.⁵²

⁵⁰ American Academy of Pediatrics, *Prevention of Childhood Lead Toxicity* (May 5, 2016) (online at <https://pediatrics.aappublications.org/content/pediatrics/early/2016/06/16/peds.2016-1493.full.pdf>); Environmental Defense Fund, *Lead in Food: A Hidden Health Threat* (June 15, 2017) (online at www.edf.org/sites/default/files/edf_lead_food_report_final.pdf); Consumer Reports, *Consumer Reports Letter to FDA on Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>).

⁵¹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁵² World Health Organization, *Lead in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf); Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/lead-and-copper-rule) (accessed Jan. 26, 2021); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

Proposed and Existing Lead Standards

Group or Agency	Standard
Environmental Defense Fund	1 ppb, especially for baby food
Consumer Reports	1 ppb in fruit juices
American Academy of Pediatrics (AAP)	1 ppb for water fountains in schools
FDA	5 ppb for bottled water
World Health Organization	10 ppb provisional guideline
EPA	15 ppb for drinking water (action level)
European Union (EU)	20 ppb for “infant formulae and follow-on formulae”
FDA	50 ppb for juice
	100 ppb for candy

The Subcommittee’s investigation has found that baby food manufacturers are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Internal testing data from Gerber, Nurture, Beech-Nut, and Hain demonstrate that all four companies sold products or used ingredients with significant amounts of lead. Only Nurture routinely tested its finished product for lead. Hain, Beech-Nut, and Gerber did not test their finished products, only their ingredients. All companies, whether they test their final products or merely their ingredients, sold baby foods even when they or their ingredients contained unsafe levels of lead.

- 1. Nurture (HappyBABY) sold finished baby food products after testing confirmed they contained as much as 641 ppb lead, over six times its already-dangerously-high internal standard.**

Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead.⁵³ Nurture also sold five other products after they tested over 50 ppb lead.⁵⁴

⁵³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁵⁴ *Id.*

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁵⁵

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition										
Blueberry Purple Carrot	Baby 7+ Months	10/25/2017	Lead	100	641	ppb	01/27/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Lead	100	580	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Apple Spinach Kiwi Cre	Baby 7+ Months	8/4/2018	Lead	100	86	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Blueberry Beet Rice Ca	Baby 7+ Months	5/22/2018	Lead	100	61	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Pea Spinach Teether	Baby 7+ Months	10/24/2019	Lead	100	55	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										
Pea Spinach Teether	Baby 7+ Months	05/07/2019	Lead	100	50	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only										

Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding the lenient EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.⁵⁶ It is not clear that even one of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

2. **Beech-Nut used ingredients containing as much as 886.9 ppb lead; Beech-Nut routinely used ingredients with high lead content, including 483 ingredients that contained over 5 ppb lead, 89 ingredients that contained over 15 ppb lead, and 57 ingredients that contained over 20 ppb lead.**

Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance, Beech-Nut used cinnamon that contained 886.9 ppb lead.⁵⁷

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entry)⁵⁸

Date	Commodity	Preshipment Lot	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	cinnamon	762	18.8	≤1000	344.5	≤1000	886.9	≤1000	Y

Beech-Nut tested and used 57 ingredients that contained over 20 ppb lead, the EU's lax standard for lead in infant formula. Beech-Nut accepted 89 ingredients that tested at or over 15 ppb lead, EPA's action level for drinking water, and 483 ingredients that tested at or over 5 ppb lead, FDA's standard for lead in bottled water.⁵⁹

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁵⁸ *Id.*

⁵⁹ *Id.*

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)⁶⁰

Date	Commodity	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	886.9	≤1000	Y
5/21/2018	Org. Cumin	644.9	≤1000	Y
8/11/2017	Org. Coriander	603.5	<1000	Y
10/11/2016	Oregano	570.4	<1000	Y
7/14/2017	Org. Cumin	231.2	≤1000	y
5/31/2017	Cinnamon	203.9	≤1000	Y
3/30/2017	Cumin	177.7	≤1000	Y
11/3/2017	Org. Cumin	167.7	≤1000	Y
12/5/2017	Org. Cinnamon	126.2	≤1000	Y
11/29/2017	Alpha Amylase	114.5	<300	Y
9/19/2018	Amylase	108.8	<300	Y
7/11/2017	Org. Lemon	102	≤160	Y
7/8/2019	Org. Cinnamon	100	≤1000	Y
7/12/2019	Org. Cinnamon	100	≤1000	Y
10/12/2017	Amylase	95.8	<300	Y
4/26/2018	Amylase	91	<300	Y
4/12/2017	Turmeric	76.3	≤1000	Y
8/27/2018	Sunflower Lecithin	71.6	≤100	Y
8/3/2017	Org. Lemon	63.7	≤160	Y

⁶⁰ *Id.*

4/11/2018	Org. Cinnamon	59	≤1000	Y
11/2/2018	S. Potato	55.3	≤15	Y
4/21/2017	Sunflower Lecithin	54.9	≤100	Y
8/15/2018	Quinoa Flour	51.6	<75	Y
11/2/2018	S. Potato	50.1	≤15	Y
10/25/2016	Lemon	47.5	≤160	Y
1/14/2019	Enzyme	47.3	<300	Y
5/31/2018	Prune Puree	41.5	≤40	Y - ER
11/6/2018	S. Potato	40.3	≤15	Y
9/29/2017	Org. Turmeric	39.3	≤1000	Y
9/13/2019	Org. Cinnamon	37.8	≤1000	Y
8/11/2017	Org. Cinnamon	36.7	≤1000	y
11/6/2018	S. Potato	35.2	≤15	Y
11/2/2018	S. Potato	34.9	≤15	Y
10/10/2018	Dehydrated Potato	32.4	<75	Y - ER
8/2/2018	Mango	32.3	≤20	Y
11/2/2018	S. Potato	31.8	≤15	Y
6/11/2018	Sunflower Lecithin	31.7	≤100	Y
8/6/2018	Prune	31.1	≤40	
8/20/2019	Sebamyl 100	30.6	<300	Y
3/19/2018	Org. Prune	30	≤40	Y
9/20/2016	Apricot	28	≤20	Y - ER
2/13/2019	Org. Prune	27.9	≤40	Y - ER

6/7/2019	Enzyme	26.3	<300	Y
6/19/2018	Org. Quinoa Flour	25.3	<75	Y - ER
2/6/2017	Vitamin Mix	24.6	<10	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
2/1/2019	Blueberry	22.7	<25	Y
11/6/2018	S. Potato	22	≤15	Y
3/18/2019	Org. Pears	21.7	<10	
6/14/2019	Sunflower Lecithin	21	≤100	Y
3/20/2018	Carrots	20	<25	Y - ER
3/20/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/16/2017	Sunflower Lecithin	20	≤100	Y
3/1/2019	Org. Cinnamon	20	≤1000	Y

3. Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead; Hain consistently used baby food ingredients with high lead content, including 88 ingredients that tested over 20 ppb lead and six ingredients that tested over 200 ppb lead.

Hain used an ingredient called vitamin pre-mix in its baby food that contained as much as 352 ppb lead.⁶¹

⁶¹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)⁶²

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Hain used six ingredients that tested above 200 ppb lead. Hain used 88 ingredients with lead levels at or over 20 ppb—the EU's standard for lead in infant formula. Hain accepted 115 ingredients that registered at or over 15 ppb—EPA's action level for drinking water. And at least 27% of Hain ingredients tested at or over 5 ppb lead, FDA's standard for lead in bottled water. None of the test results showed an ingredient below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

Hain's Raw Material Pre-Shipment Test Data History (Excepted Entries for Ingredients Above 200 ppb Lead)⁶³

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	60.5	100	352
Jan/19/2018	Grain Millers	471138	Org Whole Wheat Fine Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	160	100	250
Dec/28/2017	Grain Millers	471011	Org Quick Oats	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	<100	100	230
Dec/27/2017	Grain Millers	55300	Org Barley Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	120	100	<100	100	230
Nov/3/2017	Starwest Botanicals	40500	Org Cinnamon Powder	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	110	100	200	100	230
Jan/22/2018	Jewel Date	14300	Org Date Paste	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	190	100	220

4. Gerber used ingredients that tested as high as 48 ppb lead; and routinely accepted ingredients containing over 20 ppb lead.

Gerber produced limited lead testing results. The results for its sweet potatoes and juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead. Gerber also used twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.⁶⁴

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

Gerber Products Company Test Results (Excerpted Entries)⁶⁵

Year	Ingredient	Lead Level (ppb)
2017	Conventional	48
2017	Organic	35
2017	Organic	34
2017	Organic	34
2018	Conventional	34
2019	Conventional	34
2019	Conventional	34
2018	Organic	25
2019	Organic	25
2018	Organic	22
2018	Organic	22
2018	Organic	21
2019	Conventional	21

The average amount of lead in Gerber's tested juice concentrates was 11.2 ppb—more than FDA's limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports' recommended limit for fruit juices.

Gerber Products Company Test Results (Excerpted Entries)⁶⁶

GERBER Products Company Test Results			Confidential Business Information
			19-Dec-19
Juice Concentrate Ingredients (Lead Results)			
Year	Ingredient		Lead (ppb)
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	29
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	26
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	25

⁶⁵ *Id.*

⁶⁶ *Id.*

C. Cadmium

Outside the context of baby food, some regulation has taken action against cadmium. For example, EPA has a limit of 5 ppb in drinking water, and FDA has set a limit of 5 ppb in bottled water.⁶⁷ These standards approach WHO's 3 ppb limit for cadmium in drinking water.⁶⁸

Groups like Healthy Babies Bright Futures have set a goal of no measurable amount of cadmium in baby food.⁶⁹ Consumer Reports has called for a limit of 1 ppb cadmium in fruit juices.⁷⁰ And the EU has set a limit ranging from 5–20 ppb cadmium for infant formula.

The Subcommittee found that baby food manufacturers sold many products with much higher cadmium content.

Proposed and Existing Cadmium Standards

Group or Agency	Standard
Consumer Reports	1 ppb in all fruit juices
World Health Organization	3 ppb for drinking water
EPA	5 ppb for drinking water
FDA	5 ppb for drinking water
European Union (EU)	5-20 ppb for infant formulae

1. Beech-Nut used ingredients in its baby food containing up to 344.55 ppb cadmium; 105 Beech-Nut ingredients tested over 20 ppb cadmium.

Beech-Nut used twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium.⁷¹ That is more than 17 times higher than the EU's lax

⁶⁷ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

⁶⁸ World Health Organization, *Cadmium in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1).

⁶⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁷⁰ Consumer Reports, *Consumer Reports Letter To FDA On Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

⁷¹ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

upper limit on cadmium in baby food. At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb cadmium—the EU’s lax infant formula upper limit.⁷²

Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)⁷³

Date	Commodity	Cadmium Result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	344.50	≤1000	Y
4/11/2018	Org. Cinnamon	225.10	≤1000	Y
5/31/2017	Cinnamon	194.30	≤1000	Y
6/8/2018	Org. Garlic	186.00	≤1000	Y
8/11/2017	Org. Cinnamon	178.20	≤1000	y
10/11/2016	Oregano	176.50	<1000	Y
12/5/2017	Org. Cinnamon	163.40	≤1000	Y
11/29/2017	Dehydrated Potato	148.40	<90	Y - ER
10/10/2018	Dehydrated Potato	146.00	<90	Y
10/10/2018	Dehydrated Potato	143.50	<90	Y - ER
7/10/2019	Spinach Puree	143.00	<180	Y
7/2/2018	Fresh Spinach	142.30	<180	Y
7/8/2019	Org. Cinnamon	140.00	≤1000	Y
7/12/2019	Org. Cinnamon	140.00	≤1000	Y
3/1/2019	Org. Cinnamon	120.00	≤1000	Y
11/29/2017	Dehydrated Potato	119.60	<90	Y - ER
9/13/2019	Org. Cinnamon	117.30	≤1000	Y
7/15/2019	Spinach	117.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y

2. Hain (Earth’s Best Organic) used ingredients in its baby food containing up to 260 ppb cadmium; 102 Hain ingredients tested over 20 ppb cadmium.

Hain used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.⁷⁴ That is thirteen times the EU’s lax upper limit on cadmium in baby food. Hain tested and used 102 ingredients that registered at or above 20 ppb cadmium—the EU’s lax upper limit.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)⁷⁵

Lab Results Date	Products Description	Status	Cadmium Spec. limit (ppb)	Cadmium Result (ppb)
Jan/19/2018	Org Barley Flour	Accepted	100	260
Jan/22/2018	IQF Org Chopped Broccoli	Accepted	100	250
Jan/23/2018	Org Date Paste	Accepted	100	220
Nov/3/2017	Org Cinnamon Powder	Accepted	100	200
Aug/21/2017	Org Brown Flax Milled	Accepted	100	190
Jan/22/2018	Org Date Paste	Accepted	100	190
Jan/18/2018	Org Yellow Papaya Puree	Accepted	100	170
Jan/19/2018	Org Whole Wheat Fine Flour	Accepted	100	160
Aug/17/2017	Org Red Lentils	Accepted	100	130
Jan/15/2018	Org Oat Flakes	Accepted	100	130
Jun/13/2018	Org Brown Flax Milled	Accepted	100	121
Jan/12/2018	Org Barley Flour	Accepted	100	110
Jun/25/2018	Org Oat Flour	Accepted	100	102
Feb/19/2019	Org Cinnamon Powder	Deviation Approved	100	102

3. Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium, the EPA's limit for drinking water.

Nurture sold multi-grain cereal with 49 ppb cadmium. Nurture sold another 125 products that tested over 5 ppb, which is the EPA's limit for drinking water.⁷⁶

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁷⁷

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Cadmium	50	49	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	1/18/2019	Cadmium	50	36	ppb	12/06/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	12/4/2020	Cadmium	50	35	ppb	10/09/19	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	11/10/2019	Cadmium	50	31	ppb	10/23/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspber	Baby 7+ Months	11/10/2019	Cadmium	50	30	ppb	10/31/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁷⁵ *Id.*

⁷⁶ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁷⁷ *Id.*

4. Gerber used carrots containing as much as 87 ppb cadmium; 75% of Gerber's carrots contain cadmium in excess of 5 ppb.

Gerber does not test all its ingredients for cadmium. Of those it does test, it accepts ingredients with high levels of cadmium. Gerber used multiple batches of carrots containing as much as 87 ppb cadmium, and 75% of the carrots Gerber used had more than 5 ppb cadmium—the EPA's drinking water standard.⁷⁸

Gerber Products Company Test Results (Excerpted Entries)⁷⁹

Year	Ingredient	Supplier	Arsenic (ppb)	Cadmium (ppb)	Mercury (ppb)	Lead (ppb)
2018	Conventional	Supplier 1		87		
2018	Conventional	Supplier 4		53		
2019	Conventional	Supplier 4		42		
2017	Conventional	Supplier 1	<2	40	<1	4

D. Mercury

Outside the context of baby food, some regulation has taken action against mercury. EPA, for example, has capped mercury in drinking water at 2 ppb.⁸⁰ Consumer advocates urge even stricter standards for baby food. For example, Health Babies Bright Futures has called for a goal of no measurable amount of mercury in baby food.⁸¹

1. Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.

Nurture sold a finished baby food product that contained 10 ppb mercury, and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA's 2 ppb standard for drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.⁸²

⁷⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁷⁹ *Id.*

⁸⁰ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

⁸¹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁸² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁸³

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition
Brown Rice Cereal Canister	Baby 6+ Months	08/16/2019	Mercury	10	10	ppb	08/20/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana Sweet Potato Tee	Baby 7+ Months	6/9/2019	Mercury	10	9.8	ppb	04/16/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Brown Rice Cereal Canister	Baby 6+ Months	04/17/2019	Mercury	10	7.3	ppb	12/04/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

2. Beech-Nut and Hain (Earth's Best Organic) did not even test for mercury in baby food; Gerber barely tests for it.

From the documents produced to this Subcommittee, it appears that neither Beech-Nut nor Hain tests their ingredients or their finished products for mercury.

Gerber only tests certain ingredients for mercury. Of the test results they presented to the Subcommittee, they only tested carrots, sweet potatoes, and lemon juice concentrate.

III. INDUSTRY SELF-REGULATION FAILS TO PROTECT CONSUMERS: NURTURE, BEECH-NUT, HAIN, AND GERBER SET THEIR OWN DANGEROUSLY HIGH INTERNAL STANDARDS FOR TOXIC HEAVY METAL LEVELS AND ROUTINELY IGNORED THEM TO SELL PRODUCTS WITH HIGHER HEAVY METAL LEVELS.

Baby food manufacturers are free to set their own internal standards for toxic heavy metal content of their products. They have set those standards at dangerously high levels and have often sold foods that exceed even those levels.

A. Nurture (HappyBABY) sets high internal standards and regularly exceeds them. Nurture admits that its toxic heavy metal testing is not for safety—it sells all products tested, regardless of its toxic heavy metal content. FDA has finalized only one standard—100 ppb inorganic arsenic in infant rice cereal—Nurture has ignored it, setting its internal standard for that product at 115 ppb.

Nurture created internal standards but did not follow them. Nurture describes these standards as “goal thresholds” that “are not used to make product disposition decisions and are not a pre-condition to product release.”⁸⁴ Instead, its testing regime is limited to monitoring the supply chain. Nurture's thresholds are not actually used to prevent products that contain high levels of toxic heavy metals from being sold.⁸⁵

⁸³ *Id.*

⁸⁴ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁵ *Id.*

Nurture does not even claim to be testing for safety—it made clear in its letter response to this Subcommittee that all products will be sold regardless of testing result: **“our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into commerce.”**⁸⁶

Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold every product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards.

As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.⁸⁷

Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Nurture’s standards “are not used to make product disposition decisions and are not a pre-condition to product release.” Instead, their testing regime is limited to monitoring the supply chain.⁸⁸

Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁸⁹

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	ppb	11/01/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	3/16/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	11/16/2018	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Purple Carrot & Blueberry Puffs	Baby 7+ Months	2/15/2019	Inorganic Arsenic	100	150	ppb	11/17/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Sweet Potato & Carrot Puffs	Baby 7+ Months	1/19/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁸⁶ *Id.*

⁸⁷ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁸⁸ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁹ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Further, Nurture appears to have misled the Subcommittee about its testing standards. As seen from Nurture's goal thresholds pictured below, Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.⁹⁰ However, in the test results that Nurture provided to this Subcommittee, it was still using 100 ppb as an internal guideline after January 2019.

This image is from Nurture's December 18, 2019, response to the Subcommittee, stating that after January of 2019, its lead threshold was 50 ppb in all baby food products:⁹¹

All of our specific goal thresholds for the referenced contaminants⁸ are set forth in the chart below.

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb
Cereals	Lead	As Consumed	50*	ppb
Cereals	Mercury	As Consumed	10	ppb
Wet Foods	Cadmium	As Consumed	50	ppb
Wet Foods	Inorganic Arsenic	As Sold	100	ppb
Wet Foods	Lead	As Consumed	50*	ppb
Wet Foods	Mercury	As Consumed	10	ppb

*Threshold lowered from 100ppb to 50ppb in January, 2019.

However, the chart below appears to show that after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a “Goal Threshold” of 100 ppb for 53 baby food products. The fact that Nurture appears to have continued using a higher standard up to nine months after it claimed to the Subcommittee to have lowered the threshold casts serious doubt on Nurture's candor in this matter.

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁹²

⁹⁰ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹¹ *Id.*

⁹² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Product Name	Parameter	Goal Threshold	Result	Unit	Date of Test Report
Blueberry Beet Rice Cakes	Lead	100	<4.0	ppb	10/14/19
Stage 3 Root Vegetable and Turkey	Lead	100	<4.0	ppb	10/11/19
Apple & Broccoli Puffs	Lead	100	5.8	ppb	10/10/19
Apple Cinnamon Oat Jar	Lead	100	<4.0	ppb	10/09/19
Apple Spinach Jar	Lead	100	<4.0	ppb	10/09/19
Kale & Spinach Puffs	Lead	100	9.7	ppb	10/09/19
Apple Mango Beet	Lead	100	<4.0	ppb	08/22/19
Pear Prune Jar	Lead	100	<4.0	ppb	08/22/19
Apple Spinach Pea & Kiwi	Lead	100	43	ppb	08/22/19
Pea Spinach Teether	Lead	100	18	ppb	08/16/19
Strawberry Yogis	Lead	100	<4.0	ppb	08/13/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	07/25/19
Banana & Pumpkin Puffs	Lead	100	6.2	ppb	07/25/19
Apples Blueberries & Oats	Lead	100	<4.0	ppb	07/24/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/24/19
Green Beans Jar	Lead	100	<4.0	ppb	07/24/19
Pears Mangoes & Spinach	Lead	100	<4.0	ppb	07/24/19
Carrots	Lead	100	<4.0	ppb	07/20/19
Pea Spinach Teether	Lead	100	23	ppb	07/11/19
Apple & Broccoli Puffs	Lead	100	11	ppb	07/11/19
Kale & Spinach Puffs	Lead	100	11	ppb	07/11/19
Mangoes	Lead	100	<4.0	ppb	07/03/19
Sweet Potatoes Jar	Lead	100	<4.0	ppb	07/03/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/02/19
Harvest Vegetables & Chicken	Lead	100	<4.0	ppb	07/02/19
Apple Rice Cakes	Lead	100	7.2	ppb	07/02/19
Blueberry Purple Carrot Greek Yogis	Lead	100	4.3	ppb	07/02/19
Apple & Broccoli Puffs	Lead	100	9.9	ppb	05/30/19
Strawberry & Beet Puffs	Lead	100	10	ppb	05/22/19
Apples & Spinach	Lead	100	<4.0	ppb	05/15/19
Clearly Crafted Apple Guava Beet	Lead	100	<4.0	ppb	05/10/19
Sweet Potato Jar	Lead	100	<4.0	ppb	05/10/19
Banana & Pumpkin Puffs	Lead	100	13	ppb	04/24/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	04/24/19
Apple Pumpkin Carrots	Lead	100	<4.0	ppb	04/12/19
Pea Spinach Teether	Lead	100	23	ppb	04/12/19
Multi-Grain Cereal Canister	Lead	100	5.2	ppb	04/12/19
Carrots	Lead	100	<4.0	ppb	04/11/19
Sweet Potato Jar	Lead	100	<4.0	ppb	04/11/19
Apple Spinach Pea & Kiwi	Lead	100	34	ppb	03/29/19
Strawberry & Beet Puffs	Lead	100	7.8	ppb	03/21/19

Banana & Pumpkin Puffs	Lead	100	5.5	ppb	03/21/19
CC Oatmeal Cereal	Lead	100	<4.0	ppb	03/18/19
Carrots & Peas	Lead	100	<4.0	ppb	03/13/19
CC Prunes	Lead	100	<4.0	ppb	03/13/19
Pears & Kale Jar	Lead	100	<4.0	ppb	03/13/19
Vegetable & Beef Medley	Lead	100	<4.0	ppb	03/07/19
Banana Sweet Potato Teether	Lead	100	12	ppb	02/19/19
Banana & Pumpkin Puffs	Lead	100	11	ppb	02/19/19
Blueberry Purple Carrot Teether	Lead	100	10	ppb	02/19/19
Mangoes	Lead	100	<4.0	ppb	02/13/19
Apple Mango Beet	Lead	100	<4.0	ppb	02/12/19
Strawberry Banana Greek Yogis	Lead	100	<4.0	ppb	02/12/19

Nurture has also ignored the only final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.⁹³

*Excerpt of December 18, 2019, Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi*⁹⁴

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb

B. Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in dangerous additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.

Beech-Nut has set an internal specification limit (listed in the chart below as “spec.”) of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.⁹⁵ As a result of

⁹³ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹⁴ *Id.*

⁹⁵ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

adopting this high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.⁹⁶ Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.⁹⁷ These far surpass any existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee's inquiry.

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)⁹⁸

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
12/20/2017	BAN 800	786	465.20	<3000	6.30	<500	<58	<5000	Y
1/23/2019	ascorbic acid	80	<5	<3000	<1	<3000	<5	<3000	Y
10/7/2017	BAN 800	673	710.90	<3000	8.30	<500	<5	<5000	Y
10/23/2017	BAN 800	712	401.40	<3000	6.10	<500	<5	<5000	Y
2/19/2018	BAN 800	120	382.00	<3000	<5	<500	<5	<5000	Y
6/12/2018	Ban 800	292	353.80	<3000	<5	<500	<5	<5000	Y
3/12/2018	BAN 800	164	29.70	<3000	<5	<500	<5	<5000	Y
2/6/2017	Vitamin Mix	76	106.90	<3000	60.30	<3000	24.6	<10	Y
1/31/2017	Vitamin Mix	72	89.40	<3000	48.20	<3000	18	≤20	Y
10/10/2019	BAN 800	680	91.10	<3000	28.40	<500	7.5	<5000	Y
12/5/2018	ascorbic acid	1084	<5	<3000	<5	<3000	6	<3000	Y
9/4/2019	BAN 800	442	59.70	<3000	11.00	<500	5.8	<5000	Y

Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient.⁹⁹

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)¹⁰⁰

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
1/11/2018	Oat Flour	38	47.00	≤40	21.80	≤20	<5	≤20	Y
1/16/2018	Coarse Oat Flour	45	45.60	≤40	20.70	≤20	<5	≤20	Y
6/22/2018	Org. Oat Flour	299	24.00	≤40	20.80	≤20	<5	≤20	Y
7/5/2018	oat flour	299	24.00	≤40	20.80	≤20	<5	≤20	
3/13/2018	Coarse Oat Flour	168	23.40	≤40	20.70	≤20	<5	≤20	Y
10/1/2019	Oat Flour	645	20.90	≤40	20.90	≤20	<5	≤20	Y
9/13/2019	Oat Flour	554	18.20	≤40	22.30	≤20	<5	≤20	Y
10/10/2018	Dehydrated Potato	816	11.30	<75	143.50	<90	32.4	<75	Y - ER
11/29/2017	Dehydrated Potato	760	9.30	<75	148.40	<90	10.1	<75	Y - ER
1/30/2018	Org. Oat Flour	73	8.50	≤40	21.70	≤20	<5	≤20	Y - ER
11/29/2017	Dehydrated Potato	749	7.60	<75	119.60	<90	<5	<75	Y - ER

Beech-Nut's explanation of why it accepted products over its own internal limits was that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's allowable limits...."¹⁰¹ However, as the cadmium examples show, Beech-Nut accepted certain ingredients in spite of their own testing results which showed that they contained over 20% more cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.¹⁰² Beech-Nut did not offer any explanation.

C. Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. Hain justified deviations above its ingredient testing standards based on "theoretical calculations," even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

Hain set an internal standard of 200 ppb arsenic for 12 ingredients, most of which were different kinds of flours. By setting this high internal standard, Hain justified accepting wheat flour and rice that contained 200 and 150 ppb arsenic.¹⁰³

¹⁰⁰ *Id.*

¹⁰¹ Letter from the President and Chief Executive Officer of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf).

¹⁰² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

¹⁰³ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁴

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Aug/3/2017	Org Kamut Flour	Accepted	200	<100
Aug/3/2017	Org Spelt Flour	Accepted	200	<100
Jul/6/2017	Org Yellow Split Pea Powder	Accepted	200	<100
Jul/5/2017	Org Quinoa Flour	Accepted	200	<100
May/26/2017	Org Soft White Wheat Flour	Accepted	200	<100
Aug/1/2017	Org Fiber Oat	Accepted	200	<100
Sep/25/2017	Org Quinoa Flour	Accepted	200	<100
Sep/12/2017	Org Spelt Flour	Accepted	200	<100
Aug/4/2017	Org Spelt Flour	Accepted	200	<100
Jul/19/2017	Org Green Lentil Flour	Accepted	200	<100
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150

Similarly, Hain set an internal limit of 200 ppb for lead in five ingredients—forty times higher than FDA's guidance for bottled water. By doing so, Hain justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead.¹⁰⁵

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁶

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Lead Spec Limit (ppb)	Lead Result (ppb)
Aug/3/2017	Montana Flour & Grains	5303053	Org Kamut Flour	Accepted		Deibel	As consumed	200	<100
Jul/19/2017	Firebird Artisan Mills	57200	Org Green Lentil Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	110
Aug/2/2017	Grain Millers	5308029	Org Brown Flax Milled	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	<100
Jul/5/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted		Deibel	As consumed	200	<100
Sep/29/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted	spec for lead was 200ppb	Deibel	As consumed	200	120

¹⁰⁴ *Id.*¹⁰⁵ *Id.*¹⁰⁶ *Id.*

Hain used four products that surpassed its internal toxic heavy metal limits. For example, it accepted cinnamon that contained 102 ppb cadmium, vitamin pre-mix that had 223 ppb arsenic and 353 ppb lead, and two rice flours that had 134 and 309 ppb arsenic.¹⁰⁷

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)¹⁰⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Feb/19/2019	Red Ape Cinnamon	40500	Org Cinnamon Powder	Deviation Approved	Accepted on deviation 20190045	Deibel	As Purchased	100	20	100	102	100	40
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C ovanco	As Purchased	100	223	100	60.5	100	352
Jun/19/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 20190127	Eurofins/C ovanco	As Purchased	100	309	100	23	100	<10
Sep/4/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 2019030 and 20190234	Eurofins/C ovanco	As Purchased	100	134	100	12.8	100	5

Hain justified these variations by claiming that the “theoretical” final goods will not surpass its internal limits. For example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.¹⁰⁹

Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)¹¹⁰

Ingredient Exp. Date		
Lot Code	19090122P	
Specification	Arsenic: 100 ppb Lead: 100 ppb	Arsenic: 223 ppb Lead: 352 ppb
Highest Percentage in Finished Good(s)	2.08%	

Despite having dangerously high levels of toxic heavy metals, Hain approved the use of this vitamin pre-mix based on a “theoretical” calculation of toxic heavy metals in the final good.¹¹¹

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf).

¹¹⁰ *Id.*

¹¹¹ *Id.*

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹²

QUALITY & FOOD SAFETY REVIEW		
Reviewed Date	11/26/2019	Select one: <input checked="" type="radio"/> Approved <input type="radio"/> Rejected <input type="radio"/> Revisions Requested
Reviewed By	[REDACTED]	
Comments	Vitamin premix is used at 2.08% in the rice cereal finished good C90001. Upon theoretical calculations including the 10% variation, the arsenic and lead levels in the finished product are below 100 ppb. Attached calculations.	

To calculate the estimated quantity of lead and arsenic in the finished good, Hain considered the percentage of rice flour and vitamin pre-mix in the finished goods, and their projected amounts of arsenic and lead. Ultimately, Hain predicted that the finished good would have roughly 85 ppb arsenic and 25 ppb lead.¹¹³

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹⁴

Item	Lot Code	Heavy Metal	Test Value (ppb)	% in formula	Hypothetical Level in finished product (ppb)	
Rice Flour	B160007680	Inorganic Arsenic	81.9	97.8	80.0982	
		Lead	17.6	97.8	17.2128	
		Cadmium	18.6	97.8	18.1908	
Vitamin Premix	19090122P	Inorganic Arsenic	223	2.08	4.6384	
		Lead	352	2.08	7.3216	
		Cadmium	60.5	2.08	1.2584	
			Theoretical Arsenic		84.7366	93.21026
			Theoretical Lead		24.5344	26.98784
			Theoretical Cadmium		19.4492	21.39412

However, it is not clear that Hain ever tested the finished good. Hain appears to have used this vitamin pre-mix with dangerously high levels of toxic heavy metals without ever confirming the finished good was actually safe to consume.

Hain made this decision four months *after* it had made a secret presentation to FDA admitting that heavily tainted vitamin premix caused dangerous levels of arsenic in its finished

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

products, which initially went undetected because Hain did not test its finished products.¹¹⁵ Hain made no effort to correct the problem. *Note: Full discussion of Hain's secret presentation to FDA appears in Section V., Parts D. and E., below.*

IV. WALMART, SPROUT ORGANIC FOODS, AND CAMPBELL REFUSED TO COOPERATE WITH THE SUBCOMMITTEE'S INVESTIGATION

Nurture, Beech-Nut, Hain, and Gerber cooperated with the Subcommittee's investigation, despite the fact that doing so exposed their reckless disregard for the health of babies. With that in mind, the Subcommittee questions why Walmart (Parent's Choice), Sprout Organic Foods, and Campbell (Plum Organics) would refuse to comply with the investigation. None of them produced testing results or specific testing standards and Sprout never even responded to the Subcommittee's repeated inquiries. The Subcommittee is greatly concerned that these companies might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

A. Walmart (Parent's Choice Brand)

Walmart refused to produce any documents showing its internal testing policies, its testing results, or how Walmart treats ingredients and/or products that surpass any internal standards.

Walmart's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

*Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?*¹¹⁶

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Parent's Choice (Walmart)	Little Hearts Strawberry Yogurt Cereal Snack - Stage 3, 9+ months	Snack - other	56.1	--	5.2	26.1	0.941	Charlottesville, VA	Walmart
Parent's Choice (Walmart)	Organic Strawberry Rice Rusks - Stage 2, 6+ months	Snack - teething biscuits & rice rusks/cakes	108	66	26.9	2.4	2.05	Charlottesville, VA	Walmart

¹¹⁵ Hain, PowerPoint Presentation to Food and Drug Administration: *FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹¹⁶ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Walmart (Parent's Choice) Baby Food that Tested High in Toxic Heavy Metals¹¹⁷**B. Campbell (Plum Organics Brand)**

Campbell refused to produce its testing standards and specific testing results to the Subcommittee. Campbell has hidden its policies and the actual level of toxic heavy metals in its products.

Instead of producing any substantive information, Campbell provided a spreadsheet self-declaring that every one of its products “meets criteria.”¹¹⁸ Campbell declined to state what those criteria are.

Campbell's Product Heavy Metal Test Results (Excerpted Entries)¹¹⁹

Product Name	Testing Date	ARSENIC	CADMIUM	LEAD	MERCURY
Plum Organics® Stage 2 Apple & Carrot, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Stage 2 Banana & Pumpkin, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty 4® Blends Strawberry Banana, Greek Yogurt, Kale, Oat & Amaranth, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Snack Bars® Strawberry, 4.02oz (Pack of 6)	10/29/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Nut Butter Bar™ Almond Butter (Pack of 5)	8/29/2018	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria

¹¹⁷ Walmart, *Parent's Choice Organic Strawberry Rice Rusks* (online at www.walmart.com/ip/Parent-s-Choice-Organic-Baby-Rusks-Strawberry-Flavored/171533478) (accessed on Jan. 26, 2021).

¹¹⁸ Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>).

¹¹⁹ *Id.*

Campbell's testing summary hides more than it reveals, since it does not show the levels of heavy metals that the testing found or the levels of heavy metals that would "meet criteria."

The Subcommittee was disturbed that, for mercury, which is a powerful neurotoxin, Campbell notes with asterisks that it has no criterion whatsoever, stating: "No specific threshold established because no high-risk ingredients are used."¹²⁰ However, despite Campbell having no mercury threshold, Campbell still marked every food as "meets criteria" for mercury.¹²¹ This misleading framing—of meeting criteria that do not exist—raises questions about what Campbell's other thresholds actually are, and whether they exist.

Campbell's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

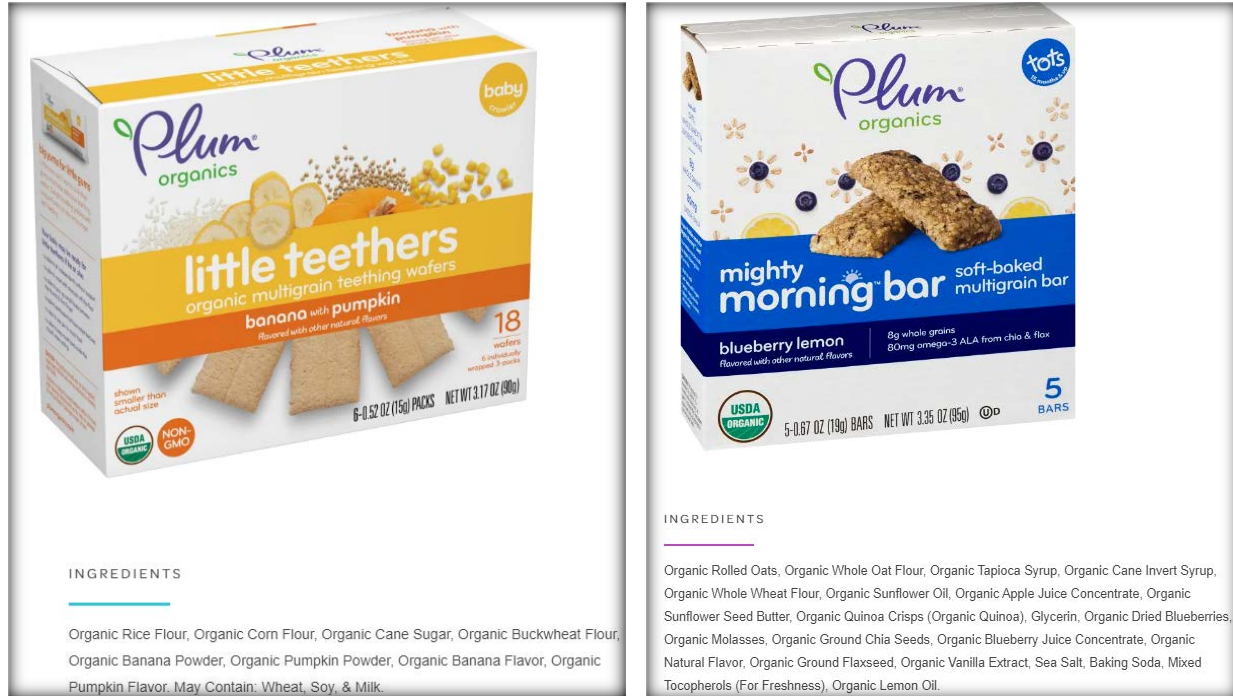
Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?¹²²

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40 *	39	3.4	24.3	<0.137	Cincinnati, OH	Kroger
Plum Organics	Little Teethers Organic Multigrain Teething Wafers - Banana with Pumpkin - Baby Crawler	Snack - teething biscuits & rice rusks/cakes	49.9	--	1.4 *	6.3	0.726	Columbia, SC	Publix

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Plum Organics' Foods That Tested High in Toxic Heavy Metals¹²³**C. Sprout Organic Foods**

Sprout Organic Foods did not respond to the Subcommittee at all. Despite numerous emails to executives and its general information email address, as well as numerous attempts to reach the Sprout central office by telephone, Sprout never responded or made contact with the Subcommittee.

Sprout Organic Foods was acquired by North Castle Partners, a Greenwich, Connecticut private equity firm, in 2015. North Castle Partners also owns such well-known brands as Curves International/Jenny Craig, Palladio Beauty Group, Mineral Fusion, Red Door Spas, Performance Bicycles, Octane Fitness, Ibex Outdoor Clothing, and Doctor's Best.¹²⁴

Whether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products.

¹²³ Plum Organics, *Little Teethers, Banana with Pumpkin* (online at www.plumorganics.com/products/banana-with-pumpkin-wafers/) (accessed Jan. 26, 2021); Plum Organics, *Mighty Morning Bar, Blueberry Lemon* (online at www.plumorganics.com/products/blueberry-lemon-bar/) (accessed Jan. 26, 2021).

¹²⁴ North Castle Partners, *Press Release: North Castle Partners Invests in Sprout Organic Foods, Inc.* (June 29, 2015) (online at www.northcastlepartners.com/wp-content/uploads/2016/01/North-Castle_Sprout-Press-Release.pdf).

Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?¹²⁵

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com

Sprout Organic Food That Tested High in Toxic Heavy Metals¹²⁶

V. FDA HAS FAILED TO CONFRONT THE RISKS OF TOXIC HEAVY METALS IN BABY FOOD. THE TRUMP ADMINISTRATION IGNORED A SECRET INDUSTRY PRESENTATION ABOUT HIGHER AMOUNTS OF TOXIC HEAVY METALS IN FINISHED BABY FOODS.

Despite the well-known risks of harm to babies from toxic heavy metals, FDA has not taken adequate steps to decrease their presence in baby foods. FDA has not issued thresholds for the vast majority of toxic heavy metals in baby foods and does not require warning labels on any baby food products. In the summer of 2019, FDA received a secret presentation from a baby

¹²⁵ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹²⁶ Sprout Organic Foods, *Quinoa Puffs, Apple Kale* (online at www.sproutorganicfoods.com/babies/6-months-and-up/plant-power-puffs/apple-kale-plant-power-puffs) (accessed Jan. 26, 2021).

food manufacturer that revealed that the commercial process of preparing finished baby foods increases their levels of toxic heavy metals. For that manufacturer, Hain (HappyBABY), the process increased inorganic arsenic levels between 28% and 93%. Yet, FDA took no apparent action.

In May 2017, FDA established the Toxic Elements Working Group with the goal of reducing exposure to toxic elements in food, cosmetics, and dietary supplements. FDA claims that the Toxic Elements Working Group is focusing on metals “because high levels of exposure to those metals are likely to have the most significant impact on public health,” and “can be especially harmful to children because of concerns about effects on their neurological development.”¹²⁷ But the working group has not resulted in new or stronger regulations to protect babies from toxic heavy metals in their food.

A. Mercury and Cadmium

FDA has acknowledged the dangers of mercury. Mercury has “no established health benefit” and has been “shown to lead to illness, impairment, and in high doses, death.”¹²⁸ FDA has acknowledged the added risk to babies and children, noting that it is: “paying special attention to children because their smaller body sizes and metabolism may make them more susceptible to the harmful effects of these metals,” including mercury.¹²⁹

Despite these statements, FDA has taken no action to limit mercury in baby food. Instead, FDA has only set mercury standards for wheat, and fish, shellfish, and crustaceans, and they are high—1,000 ppb.¹³⁰ There are no FDA protections for mercury in baby food.

The lack of FDA action on mercury standards stands in contrast to other regulators. The EPA, for example, set a limit of 2 ppb mercury in drinking water, even after taking into account the cost of attainment for industry.¹³¹

¹²⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021); Food and Drug Administration, *What FDA Is Doing to Protect Consumers from Toxic Metals in Foods* (Apr. 20, 2018) (online at www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods).

¹²⁸ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

¹²⁹ *Id.*

¹³⁰ Food and Drug Administration, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (Aug. 2000) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed).

¹³¹ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

Similarly, FDA has taken no action on cadmium in baby food. FDA has issued only one guideline for cadmium, and that is a limit of 5 ppb for bottled water.¹³² The EU has instituted a limit of 10-15 ppb for infant formula.¹³³

B. Lead

FDA acknowledges that there is “no identified safe blood lead level” and that lead is especially dangerous to children:

Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. High levels of lead exposure can seriously harm children’s health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹³⁴

FDA has taken action on bottled water, limiting lead to 5 ppb.¹³⁵ FDA has also taken steps toward regulating lead content in products for older children. FDA has released guidance recommending a maximum lead level of 100 ppb in candy likely to be consumed by children, and 50 ppb in some juices.¹³⁶ It is not sound logic to say that water is unsafe to drink if it contains over 5 ppb lead, but candy and fruit juice can be ten and twenty times higher than that limit.

Unfortunately, it appears that FDA designed these limits to be protective of industry. In its “Supporting Document for Recommended Maximum Level for Lead in Candy,” FDA repeatedly emphasizes achievability by industry, as opposed to safety for children:

- “FDA believes that sugar-based candy products *can be made* with lead levels below” [100 ppb].”
- “We believe *that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb] lead.”
- “We believe that, *if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb].”

¹³² 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

¹³³ European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

¹³⁴ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁵ *Id.*

¹³⁶ *Id.*

- “[E]ven for high-chili-content candy and powdered snack mix products, *we believe that candy with appropriately sourced ingredients will not exceed* [100 ppb] lead.”
- “We believe that *if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed* [100 ppb] lead.”¹³⁷

But FDA has failed to regulate lead levels in baby foods. Manufacturers are free to set their own limits. Hain, for example, used internal soft limits of 100 and 200 ppb lead for the majority of its ingredients.

FDA *has* created what it calls an Interim Reference Level (IRL) for lead, but this standard does not apply to manufacturers and is unhelpful for parents purchasing baby food. An Interim Reference Level is what FDA calls a calculation of “the maximum daily intake for lead from food.”¹³⁸ Above this limit, a person or baby’s blood level would reach a “point of concern.” FDA’s current IRL is 3 µg per day for children. This standard, though perhaps helpful to FDA in researching and evaluating how lead affects our nation’s children, is unworkable for parents. For this standard to be useful to a parent, they would need to know:

- what a µg is (it stands for a microgram);
- how much lead is in each product they are serving their baby;
- how much lead their child is exposed to through tap water; and
- how much lead is in their local environment, such as through lead-based paints.

Obtaining this information is currently impossible for parents because baby food manufacturers do not publicly provide information on the amount of lead in their products. Given the information gaps parents face, it would be most appropriate for FDA to promulgate clear rules for baby food manufacturers that limit the amount of lead in baby food.

C. Arsenic

In the context of arsenic in baby food, there are only two FDA regulations for specific products—an unenforceable draft guidance issued in July 2013, but never finalized, recommending an action level of 10 ppb for inorganic arsenic in single-strength (ready to drink) apple juice, and an August 2020 final guidance, setting an action level for inorganic arsenic in infant rice cereals at 100 ppb.¹³⁹

¹³⁷ Food and Drug Administration, *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children* (Nov. 2006) (online at www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small) (emphasis added).

¹³⁸ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁹ Food and Drug Administration, *Draft Guidance for Industry: Action Level for Arsenic in Apple Juice* (July 2013) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-arsenic-apple-juice); Food and Drug Administration, *Guidance for Industry: Action Level for*

The first problem with these standards is that they cover only a small sliver of the foods babies eat.

The second problem is that they are far too lax to be protective of babies. There is no established safe level of inorganic arsenic consumption for babies. Arsenic exposure has a “significant negative effect on neurodevelopment.”¹⁴⁰ FDA acknowledged that “Low-to-moderate levels of inorganic arsenic appear to be associated with adverse health effects during childhood.”¹⁴¹ Children exposed to water with an arsenic concentration of just 5 ppb “showed significant reductions in Full Scale, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.”¹⁴² This suggests that 5 ppb may be an important threshold, or that the threshold of safety may fall far below that.

Healthy Babies Bright Futures has called for a goal of no measurable amount of inorganic arsenic in baby food.¹⁴³ Consumer Reports suggests that the level of inorganic arsenic should be set as low as 3 ppb for water and fruit juices.¹⁴⁴

FDA has already set inorganic arsenic levels at 10 ppb for bottled water.¹⁴⁵ EPA has similarly set a 10 ppb inorganic arsenic cap on water, as have the European Union and the World Health Organization.¹⁴⁶

Inorganic Arsenic in Rice Cereals for Infants (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

¹⁴⁰ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

¹⁴¹ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

¹⁴² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹⁴³ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹⁴⁴ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

¹⁴⁵ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

¹⁴⁶ Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

FDA is fully aware of the dangers that inorganic arsenic presents to young children, stating that:

There is growing evidence ... that exposure to inorganic arsenic during...infancy...may increase the risk of adverse health effects, including impaired development during...childhood and neurodevelopmental toxicity in infants and young children, and that these adverse effects may persist later in life [C]hildren may likewise be particularly susceptible to neurotoxic effects of inorganic arsenic, e.g., as manifested in intelligence test results in children Also, children three years and younger have the highest exposure to inorganic arsenic because they have 2-3-fold higher intakes of food on a per body mass basis as compared to adults. Therefore, a child's daily exposure to contaminants in food, such as inorganic arsenic in rice, could potentially be much higher than that of adults.¹⁴⁷

Yet, in the one category of baby food for which FDA has finalized a standard—infant rice cereal—it set the maximum inorganic arsenic content at the dangerous level of 100 ppb.

Why did FDA set its level so high? Because in developing the limit, FDA was focused on the level of inorganic arsenic that would cause cancer. FDA disregarded the risk of neurological damage, which happens at a much lower level. In its 2016 Risk Assessment Report, FDA was able to quantify the risk of lung and bladder cancer that inorganic arsenic presents. It was not able to quantify the risks of neurological development for infants.¹⁴⁸ As a result, the 100 ppb limit is too high to adequately protect infants and children from the effects of inorganic arsenic.

The third problem is that FDA's piecemeal approach of setting different inorganic arsenic standards for different products is logically unsound. There can be only one safe level for inorganic arsenic in the foods that babies consume. All finished baby food products should accord with this safe level.

Aside from these guidance documents for infant rice cereal and apple juice, FDA does not regulate toxic heavy metals in other baby food products.

One example of how this approach is failing is with FDA's decision to release draft guidance for apple juice, but not any other fruits juices. Based on the testing results the Subcommittee reviewed, baby food companies routinely exceed this draft limit of 10 ppb in other types of commonly consumed juices. Gerber, for example, used grape juice concentrate registering at 39 ppb inorganic arsenic. But because it was grape juice, as opposed to apple

¹⁴⁷ Food and Drug Administration, *Supporting Document For Action Level For Inorganic Arsenic In Rice Cereals For Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁴⁸ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

juice—which, from a safety perspective, is a distinction without a difference—Gerber incorporated in its products juice concentrate with high arsenic levels.

The fourth problem with FDA’s piecemeal approach is that it appears designed to be protective of baby food manufacturers. In developing the infant rice cereal limit of 100 ppb, FDA considered an “achievability assessment.” The achievability assessment considered “manufacturers’ ability to achieve hypothetical maximum limits for inorganic arsenic in infant rice cereals....”¹⁴⁹ FDA considered samples taken from three time periods: 2011-2013, 2014, and 2018. As shown below, over time, the number of samples that tested under 100 ppb inorganic arsenic increased from 36% to 76% of the total number of samples. FDA noted that this increase meant “alternate sources of rice are available to enable infant rice cereal manufacturers to supply the market and meet the” 100 ppb level.¹⁵⁰ In short, FDA’s standard reflects manufacturers’ ease of compliance, rather than babies’ safety.

If it is not possible, or it is exceedingly costly, to source ingredients like rice that achieve a safe level, then baby food manufacturers should find substitutes for those ingredients. Our nation’s children should not bear lifelong health burdens because of a manufacturer’s preference for tainted ingredients.

D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.

On August 1, 2019, the Trump administration received a secret industry presentation that disclosed higher risks of toxic heavy metals in finished baby food products. Hain (Earth’s Best Organic) revealed the finding in a presentation to FDA entitled “FDA Testing Result Investigation.”¹⁵¹

¹⁴⁹ Food and Drug Administration, *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁵⁰ *Id.*

¹⁵¹ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).



Hain revealed that half (10 of 21) of the finished rice products that Hain tested contained 100 ppb or more of inorganic arsenic—exceeding FDA’s standard for infant rice cereal. One product contained almost 30% more, registering at 129 ppb inorganic arsenic.

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

Hain’s average level of inorganic arsenic in its finished rice foods was 97.62 ppb, which nearly matches FDA’s dangerously high 100 ppb level for inorganic arsenic for infant rice cereal.

Hain claims that it “revised its internal policies and testing standards to conform to FDA’s non-binding recommendations.”¹⁵² In 2016, FDA instituted draft guidance (which is now final) for inorganic arsenic in infant rice cereal at the dangerously high level of 100 ppb. However, Hain has not consistently abided by those limits.

FDA also learned that Hain’s policy to test ingredients underrepresented the levels of toxic heavy metals in its finished baby foods. Hain’s finished products contained between 28% and 93% more inorganic arsenic than Hain estimated they would based on Hain’s ingredient

¹⁵² Letter from Kelly B. Kramer, Counsel for The Hain Celestial Group, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9_Redacted.pdf).

testing method.¹⁵³ Hain found higher levels of arsenic in *all* finished foods tested for this FDA presentation than were reflected in tests of individual raw ingredients. This revelation means that every single finished good containing brown rice had more arsenic than the company's estimates, which were based on testing the raw ingredients.

After seeing these results, FDA was put on notice that finished baby foods pose an even higher risk to babies than reflected in company tests of the raw ingredients that go into those finished products.

Final Product Data Compared to Raw Ingredient Data, From Hain's Presentation to FDA¹⁵⁴

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data									
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result				
1017814	3/2/19	BN A 0636	94	80.3	43%	9/8/17	199987	B160004661	Total Arsenic	54	56.3				
1038929		BN C 1139	83					B160004870	Total Arsenic	58					
1039633		BN F 1648	64				B160004759	Total Arsenic	57						
							B160004659	Total Arsenic	54						
1039750	3/8/19	BN E	74	74.0	29%	9/14/17	200408	B160004871	Total Arsenic	60	57.3				
								B160004870	Total Arsenic	58					
								B160004661	Total Arsenic	54					
1041752	3/20/19	BN G	92	96.0	57%	9/26/17	200651	B160005149	Total Arsenic	65	61.3				
1037933		BN E 1536	67					B160004873	Total Arsenic	58					
1041751	3/21/19	BN B 0832	108			9/27/17		B160005157	Total Arsenic	62					
1038677		BN B 0932	116					B160004871	Total Arsenic	60					
1026932	4/11/19	BN D 1248	97	100.0	69%	10/18/17	201873	B160005148	Total Arsenic	61	59.0				
1044380		BH C	100					B160004872	Total Arsenic	55					
								B160005152	Total Arsenic	61					
								B160005305	Total Arsenic	69					
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005306	Total Arsenic	76	67.0				
								B160005512	Total Arsenic	62					
								B160005152	Total Arsenic	61					
1024210	6/6/19	BN I 2241	94	101.0	61%	12/13/17	206697	B160005515	Total Arsenic	63	62.7				
547103		BN I 2339	115			12/14/17		B160005513	Total Arsenic	60					
1013927	6/7/19	BN E 1540	92												
1026516		BN H 2123	104			12/15/17		B160005150	Total Arsenic	65					
1074288	6/8/19	BNE 1406	105												
1035738	6/13/19	BN J 0000	96			12/20/17									
1047511	6/27/19	BN C 1142	100	100.0	56%	1/3/18	208226	B160006190	Inorganic Arsenic	73	64.0				
								B160005581	Total Arsenic	55					
1063061	7/19/19	BN J	115	115.0	43%	1/25/18	208594	B160006189	Inorganic Arsenic	81	80.5				
								B160006191	Inorganic Arsenic	80					
1027437	8/18/19	BN A 0703	97	97.0	28%	2/24/18	210374	B160006265	Inorganic Arsenic	77	75.7				
								B160006263	Inorganic Arsenic	74					
								B160006260	Inorganic Arsenic	76					
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	B160007235	Inorganic Arsenic	66	82.5				
								B160006755	Inorganic Arsenic	99					

Hain admitted to FDA in its presentation that "Brown Rice Flour testing results do not appear to be correlated to finished good results data."¹⁵⁵ They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

¹⁵³ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

What can account for this increase in inorganic arsenic from the time the ingredients are tested to the time the products are finished? Hain conveyed to FDA that the cause of the increase was Hain's use of a dangerous additive, stating: "Preliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor." Although this additive may only make up roughly 2% of the final good, Hain suggested it was still responsible for the spike in the levels of inorganic arsenic in the finished baby food.¹⁵⁶

Hain's finding accords with the Subcommittee's own. In the test results we reviewed, Hain used vitamin pre-mix that contained 223 ppb arsenic.¹⁵⁷ This ingredient also contained 352 ppb lead, a matter not even addressed in the FDA presentation.

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)¹⁵⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Therefore, naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

FDA did not appear to take any unplanned actions on behalf of babies' safety after it received Hain's presentation. FDA did finalize a previously planned guidance, setting a limit of 100 ppb inorganic arsenic in infant rice cereal. But it did not initiate regulation of additives like Hain's vitamin/mineral pre-mix. Moreover, it has not mandated that baby food manufacturers test finished goods.

E. Corporate Testing Policies Hide the Truth: In Addition to Hain, Beech-Nut and Gerber Also Fail to Test Finished Product, Risking an Undercount of Toxic Heavy Metals in Their Finished Baby Foods.

Hain (Earth's Best Organic) revealed to FDA that its policy to test only its ingredients, and not its final product, is underrepresenting the levels of toxic heavy metals in its baby foods. Unfortunately, Hain is not alone. The majority of baby food manufacturers, including Beech-Nut and Gerber, employ the same policy of testing only ingredients.¹⁵⁹ That policy recklessly

¹⁵⁶ *Id.*

¹⁵⁷ Hain, Raw Material Pre-Shipment Test Data History (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

¹⁵⁸ *Id.*

¹⁵⁹ Letter from the President and CEO of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf) ("we do not test finished goods"); Letter from the Chief Executive Officer of Gerber Products Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 19,

endangers babies and children and prevents the companies from even knowing the full extent of the danger presented by their products.

As the Hain presentation lays bare, ingredient testing does not work. Hain's finished baby foods had more arsenic than their ingredients 100% of the time—28-93% more inorganic arsenic.¹⁶⁰ That means that only testing ingredients gives the false appearance of lower-than-actual toxic heavy metal levels.

VI. RECOMMENDATIONS AND CONSIDERATIONS FOR INDUSTRY, PARENTS, AND REGULATORS: DO HIGHLY TAINTED INGREDIENTS LIKE RICE BELONG IN BABY FOOD?

Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell unsafe products. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and federal regulators have broken the faith.

Step one to restoring that trust is for manufacturers to voluntarily and immediately reduce the levels of toxic heavy metals in their baby foods to as close to zero as possible. If that is impossible for foods containing certain ingredients, then those ingredients should not be included in baby foods.

One example of an ingredient that might not be suitable for baby foods is rice. Throughout this report, rice appeared at or near the top of every list of dangerous baby foods.

- For Hain (Earth's Best Organic), organic brown rice was the ingredient that tested highest in inorganic arsenic—309 ppb. Indeed, the majority of Hain ingredients that exceeded 100 ppb inorganic arsenic in testing (13 of 24) were organic brown rice flour.¹⁶¹
- For Beech-Nut, the majority of its ingredients that tested over 100 ppb inorganic arsenic (27 of 45) were rice-based (either rice, rice flour, or organic rice).¹⁶²

2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7_Redacted.pdf) (Gerber's policy is to "regularly test our ingredients, and periodically test... finished goods"); Hain, *Testing And Release Procedure For Baby Food Ingredients* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/8_Redacted.pdf) (Hain only tests raw ingredients; their testing policy applies only to ingredients and the vast majority of the testing information they provided to the Subcommittee was raw ingredient testing.).

¹⁶⁰ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁶¹ *Id.*

¹⁶² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

- A significant number of the Nurture products that exceeded 100 ppb inorganic arsenic were rice products.¹⁶³
- Gerber used 67 batches of rice flour with over 90 ppb inorganic arsenic.¹⁶⁴

Further, rice and rice flour constitute a large proportion by volume of the baby foods that contain them. Therefore, increased toxic heavy metal levels in rice and rice flour could have a significant impact on the safety of the finished product.

If certain ingredients, like rice, are highly tainted, the answer is not to simply lower toxic heavy metal levels as much as possible for those ingredients, the answer is to stop including them in baby foods. The Subcommittee urges manufacturers to make this change voluntarily.

Similar considerations must be made for other ingredients that consistently contain higher levels of toxic heavy metals—ingredients like cinnamon, amylase, BAN 800, and vitamin premix. Manufacturers suggest that these additives, though high in toxic heavy metals, are not a concern because they make up a low percentage of the final food product. However, those manufacturers do not test their final food products, which is the only way to determine safety. Manufacturers should voluntarily commit to testing all of their finished baby food products, as opposed to just the ingredients. If they refuse, FDA should require them to do so.

The Subcommittee recommends the following:

- **Mandatory Testing:** Only one of the companies reviewed by the Subcommittee routinely tests its finished baby foods, even though the industry is aware that toxic heavy metals levels are higher after food processing. Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.
- **Labeling:** Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels.
- **Voluntary Phase-Out of Toxic Ingredients:** Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.
- **FDA Standards:** FDA should set maximum levels of inorganic arsenic, lead, cadmium, and mercury permitted in baby foods. One level for each metal should apply across all baby foods. The level should be set to protect babies against the neurological effects of toxic heavy metals.
- **Parental Vigilance:** Parents should avoid baby food products that contain ingredients testing high in heavy metals, such as rice products. The implementation of recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

¹⁶³ Nurture, *Heavy Metal Test Results For Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

¹⁶⁴ Gerber, *Raw Material Heavy Metal Testing* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

VII. CONCLUSION

The Subcommittee's investigation proves that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.

Last year, the Trump administration ignored new information contained in a secret industry presentation to federal regulators about toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain, the maker of Earth's Best Organic baby food, which revealed that finished baby food products contain even higher levels of toxic heavy metals than estimates based on individual ingredient test results. One heavy metal in particular, inorganic arsenic, was repeatedly found to be present at 28-93% higher levels than estimated.

The time is now for FDA to determine whether there is any safe exposure level for babies to inorganic arsenic, lead, cadmium, and mercury, to require manufacturers to meet those levels, and to inform consumers through labels.

BGC.13618

CAUSE NO. 111847-CV

SARAH PALMQUIST, INDIVIDUALLY	§	IN THE DISTRICT COURT
AND AS NEXT FRIEND OF E.P., A	§	
MINOR, AND GRANT PALMQUIST	§	
	§	
v.	§	149th JUDICIAL DISTRICT
	§	
THE HAIN CELESTIAL GROUP, INC.,	§	
AND	§	
WHOLE FOODS MARKET, INC.	§	BRAZORIA COUNTY, TEXAS

DEFENDANT'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW **THE HAIN CELESTIAL GROUP, INC.**, Defendant named in the above entitled and numbered cause, and files this its Original Answer, and for same would respectfully show unto the Court as follows:

I.

GENERAL DENIAL

Defendant denies each and every, all and singular, the material allegations contained within Plaintiffs' pleadings and demands strict proof thereof.

II.

JURY DEMAND

In accordance with Rule 216 of the Texas Rules of Civil Procedure, Defendant demands a trial by jury. Simultaneously with the filing of this demand, a jury fee is being paid on behalf of this Defendant.

WHEREFORE, PREMISES CONSIDERED, Defendant **THE HAIN CELESTIAL GROUP, INC.** prays that the Plaintiffs take nothing by this suit, that Defendant go hence with its costs without delay, and for such other and further relief, both general and special, at law and in equity, to which Defendant may show itself justly entitled.

Respectfully submitted,

FEE, SMITH, SHARP & VITULLO, L.L.P



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THE HAIN CELESTIAL GROUP, INC.**

CERTIFICATE OF SERVICE

THIS WILL CERTIFY that a true and correct copy of the foregoing instrument has been served to all attorneys of record in this cause of action on the 5th day of April, 2021.



BRIAN G. CANO